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HOUSE OF REPRESENTATIVES
REPORT
No. 94-1484

CLINICAL LABORATORY IMPROVEMENT ACT OF 1976

REPORT

BY THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

together with

MINORITY AND ADDITIONAL VIEWS AND INCLUDING THE CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

[To accompany H.R. 14319]

SEPTEMBER 8, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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SEPTEMBER 8, 1976.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. STAGGERS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 14319]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 14319) to amend the Public Health Service Act and the Social Security Act to revise and improve the authorities under those Acts for the regulation of clinical laboratories, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment strikes out all after the enacting clause and inserts in lieu thereof a substitute text which appears in italic type in the reported bill.

LEGISLATIVE BACKGROUND

Legislation to amend the Public Health Service Act to revise and improve the authority under that Act for the regulation of clinical laboratories, H.R. 11341, was introduced on December 19, 1975, by Mr. Rogers, Chairman of the Subcommittee on Health and the Environment. Hearings were conducted on H.R. 11341 and all similar or identical bills on March 23, 24, 25, and 26, 1976. The bill was subsequently considered in open executive sessions by the Subcommittee on Health and the Environment, amended, reported, and reintroduced as a clean bill, H.R. 14319, on June 10, 1976 by Mr. Rogers and nine members of the Subcommittee. H.R. 14319 was considered by the Interstate and Foreign Commerce Committee on August 24, 25, and 26, 1976, amended, and ordered reported on August 26, 1976.

Summary of Legislation

H.R. 14319, the Clinical Laboratory Improvement Act of 1976, would amend the Public Health Service Act and the Social Security Act to revise and improve the authorities under those Acts for the regulation of clinical laboratories. Briefly, it would do the following:

1. It would require the Secretary of Health, Education, and Welfare to establish national standards for clinical laboratories (defined as any facility for examining materials derived from the human body for purposes of diagnosis, prevention or treatment of disease or for assessing human health) designed to assure accurate procedures and services. These standards would—

(a) require laboratories to maintain quality control programs,

(b) require laboratories to maintain records, equipment and facilities as necessary for effective operation,

(c) include requirements for periodic proficiency testing of laboratories,

(d) prescribe qualifications for directors, supervisors, technologists and technicians, and

(e) contain adequate provisions for the enforcement of the established standards.

Such standards are to be proposed within 180 days after the date of enactment and promulgated within one year after the date of enactment.

2. It would require all clinical laboratories to comply with the national standards with the following five exceptions:

(a) standards would not take effect for intrastate laboratories until two years after their promulgation;

(b) requirements with respect to qualifications of supervisory personnel and technologists are to be delayed for four years with respect to a clinical laboratory which the Secretary determines is located within a rural area in which supervisory personnel and technologists with the prescribed qualifications are not available, which performs services only for hospitals and health professionals located within the area, and which provides assurances that it will take action to train or employ individuals who will meet the qualifications;

(c) national standards would not apply to clinical laboratories located in the office of, and operated by, physicians, dentists or podiatrists in which the only tests or procedures which are performed are tests or procedures performed by such practitioners in connection with the treatment of their patients;

(d) the Secretary would be required to exempt, upon application, clinical laboratories located in the office of a group of not more than five physicians, dentists or podiatrists in which the only tests or procedures performed are by such practitioners or routine tests or procedures performed by non-practitioners;

(e) the Secretary would be required to exempt laboratories in which the only tests or procedures which are performed are tests or procedures for research; and

(f) national standards would not apply to clinical laboratories in which the only tests or procedures which are performed are tests or procedures for the purpose of writing insurance contracts.

3. It would permit a State to assume primary enforcement responsibility for the regulation of laboratories located within or doing business within its jurisdiction in instances in which the State has adopted standards that are no less stringent than the national standards and has adopted and is implementing an adequate enforcement mechanism.

4. It would require the Secretary to establish a system of licensure of clinical laboratories and sets forth the circumstances under which such a license could be suspended or revoked.

5. It would authorize the Secretary and any State with primary enforcement responsibility to enter into agreements with qualified public or nonprofit private entities to inspect and administer proficiency tests and periodic examinations required by the legislation.

6. It would provide that individuals who solicit or accept a specimen for a laboratory which does not have a license shall be fined not more than $10,000 or imprisoned for not more than one year, or both. It further provides that owners or operators of clinical laboratories who engage in false, fictitious or fraudulent billing practices under Medicaid or Medicare shall be fined not more than $10,000 or imprisoned for not more than three years, or both.

7. It would prohibit an employer from discharging or otherwise discriminating against an employee because the employee commenced or testified in a Federal or State proceeding relating to violations of the legislation, and it would require the Secretary of Labor to investigate charges of discrimination and authorize him to order reinstatement and damages in appropriate instances.

8. It would authorize the Secretary, or his designee, upon written notice, to inspect any clinical laboratory subject to national standards.

9. It would authorize the Secretary to make grants of up to 75% of costs to States with primary enforcement responsibility to assist such States in meeting the costs of administering and enforcing their programs and would authorize $3.75 million for each of fiscal years 1979, 1980, and 1981 for such purposes. Such sums would be in addition to funds made available to States under the Social Security Act to inspect Medicare and Medicaid laboratories.

10. It would establish within the Department of Health, Education, and Welfare an advisory council on clinical laboratories, and an identifiable administrative unit within the Department, under the direct supervision of the Assistant Secretary for Health, which shall be responsible for coordination of the regulatory functions authorized by the legislation and the laboratory certification and regulatory functions authorized by the Social Security Act.

11. It would authorize the Secretary, acting through the Center for Disease Control, to contract with State public health laboratories to assist such laboratories in the conduct of tests of human tissue to determine the presence of carcinogenic and other toxic substances and would authorize $3 million for fiscal year 1978 for such purposes.

12. It would require the Secretary to report to the Congress annually with respect to the accuracy and costs of laboratory tests and procedures during the previous fiscal year.

13. It would amend the Social Security Act as follows:

(a) to provide that reimbursement for laboratory services (other than such services provided in a hospital) could not include any element of a cost or charge which is a commission,

finders fee, or an amount payable for rental or lease of a facility which amount is unrelated or disproportionate to the fair market value of the facility or where such amount is set as a percent or fraction of the cost of laboratory services;

(b) to authorize a State to engage in competitive bidding for the purpose of purchasing laboratory services;

(c) to require that, to be eligible for reimbursement under the Medicaid program, a laboratory must bill at rates no higher than its lowest rates for the same services; and

(d) to provide that violations of the antifraud provisions of titles XVIII and XIX of such Act are felonies, not misdemeanors, punishable by a maximum sentence of three years.

14. It would require the Secretary to conduct a study respecting certification of laboratory personnel and a study of financial arrangements made by hospitals for clinical laboratory services, and to provide the Congress with a summary of the information received under applications for exemption submitted by physician, dentist, and podiatrist owned laboratories.

Cost of Legislation

As reported by the Committee, H.R. 14319 provides authorizations of appropriations for fiscal years 1978, 1979, 1980, and 1981 in the amounts shown in the following table.

AUTHORIZATIONS OF APPROPRIATIONS (NEW OBLIGATIONAL AUTHORITY) FOR FISCAL YEARS 1978–81 PROVIDED BY H.R. 14319

[In millions of dollars]

	Fiscal year—				
	1978	1979	1980	1981	Total
Grants to States with primary enforcement responsibility		3.75	3.75	3.75	11.25
Contracts with State laboratories for toxicological testing	3.0				3.0
Total	3.0	3.75	3.75	3.75	14.25

These authorizations may be compared with the total costs of laboratory services in the United States in 1975 of more than $8 billion and the projected cost in 1980 of nearly $15 billion. Further, as set forth in the Congressional Budget Office estimate which appears later in this report, the projected savings which would begin to accrue upon enactment of this legislation are estimated at $251.6 million by 1981.

Background and Need for Legislation

INTRODUCTION

The American health care system relies heavily upon the services of clinical laboratories to analyze and provide information on samples of body tissues or fluids to enable physicians and other health professionals to better diagnose and determine proper therapy for their patients. With advances in medical technology, a growing number of conditions can be detected through laboratory testing of body specimens, and health professionals are becoming increasingly de-

pendent on accurate laboratory test results in order to properly treat their patients.

The cost of the health care system's dependence upon clinical laboratory services is staggering. In 1971, an estimated 2.9 billion tests were performed at a cost of $5.6 billion. By 1975, nearly 5 billion tests were conducted by the more than 65,000 clinical laboratories in this country, or an average of more than twenty tests per person, at a total cost of approximately $12 billion, more than ten percent of every dollar spent for health care services last year. By 1980, it is estimated that some 8.8 billion tests will be conducted annually at a cost of about $15 billion. While expenditures for all health care services have been increasing at a rate of 11 percent per year, laboratory services costs have been expanding at the rate of 15 percent per year.

The clinical laboratory industry in the United States has three unfortunate characteristics. First, existing procedures for regulating the quality of clinical laboratories is irregular at best. Second, the quality of clinical laboratory procedures in the United States is grossly inadequate. Third, there is growing evidence of fraud and abuse within the industry, particularly in connection with the Medicaid program.

HISTORY OF REGULATION OF CLINICAL LABORATORIES

Federal Regulation

With the enactment of the Social Security Amendments of 1965 (P.L. 89–97) and the establishment of the Medicare program, the Federal government took its initial regulatory action in the laboratory services area. Standards, including requirements for licensure where applicable under State law, were developed for laboratories which received Federal funds under Medicare and which were not located in hospitals accredited by the Joint Commission on Accreditation of Hospitals (JCAH) or the American Osteopathic Association (AOA). Under the 1965 Act, the Secretary was authorized to enter into agreements with the States to certify compliance by non-JCAH or AOA accredited laboratories. Standards established under Medicare could be no higher than those of the JCAH or AOA, and JCAH and AOA accredited laboratories were automatically certified as having met the requirements of the law and could not be inspected, even on a sample basis, under the auspices of the Medicare program. It was not until the passage of the Social Security Amendments of 1972 (P.L. 92–603) that the Secretary was authorized to set higher standards than those of the JCAH (although to date he has not done so) and could authorize the inspection, only on a sample basis, of JCAH accredited laboratories. Current Medicaid regulations require laboratories which receive reimbursement under Medicaid to be certified in accordance with Medicare criteria or to meet, at the option of the State, equally stringent standards.

The Clinical Laboratories Improvement Act of 1967 (P.L. 90–174), known as CLIA '67, represents the second major Federal effort to improve the quality of laboratory medicine. It required the licensure and inspection of laboratories engaged in interstate commerce and required such laboratories to meet national standards designed to assure consistent performance of accurate laboratory procedures and

services, including standards with respect to quality control programs; qualifications of personnel; maintenance of records, equipment, and facilities necessary to proper and effective operation; and proficiency testing programs. It exempted from the licensure requirements those laboratories located in JCAH and AOA accredited hospitals and those inspected and accredited by the JCAH or AOA, those inspected and accredited by the College of American Pathologists (CAP) or other approved national accreditation organizations, if the Secretary determined that the standards applied by such inspecting and accrediting entities were at least as stringent as the national standards. In addition, it exempted those laboratories located in health professionals' offices which performed tests solely as an adjunct to the treatment of the patients of such health professionals, and laboratories which performed tests solely for the purpose of determining eligibility for insurance coverage.

As readily apparent from the preceding discussion, both the locus and extent of regulation of clinical laboratories vary widely depending on the location of a laboratory and its clients.

Any laboratory engaged in interstate commerce is inspected and licensed by the Center for Disease Control of the U.S. Public Health Service and must comply with the stringent standards of the Clinical Laboratories Improvement Act of 1967 (CLIA '67). Exemptions from the inspection and licensing requirements are made for those laboratories inspected and accredited by the American College of Pathologists and those located within the State of New York, both of whose standards have been determined by the CDC as being at least as stringent as the national standards. JCAH and AOA accredited hospital-based laboratories which are engaged in interstate commerce are not exempt from licensure requirements under CLIA '67 because the CDC has determined that the standards of the JCAH and the AOA are not as stringent as the national standards. An interstate laboratory which is reimbursed under Medicare or Medicaid is subject to certification by State authorities; however, under an agreement between the CDC and the Social Security Administration, CDC inspects and certifies such laboratories in conjunction with its own inspection and licensure activities. Finally, an interstate laboratory may also be required to comply with the provisions of individual State laws which may contradict the national standards.

Of the 7,000 hospital-based laboratories which receive reimbursement under the Medicare or Medicaid programs, 4,400 are located in hospitals accredited by the JCAH and are subject to inspection and certification by that accrediting organization. By all accounts, JCAH inspection activities with respect to hospital-based laboratories are not satisfactory, although the Secretary has not determined that the JCAH standards are not the equivalent of existing Medicare standards, (although he has determined them to be inferior to CLIA '67 standards). A recent report by the Social Security Administration cited serious deficiencies in the JCAH survey process; concern has also been voiced as to the superficial nature of JCAH inspections, particularly in instances in which the laboratory participates in a CAP proficiency program, as well as to the lack of expertise in laboratory practices and activities of most JCAH inspectors.

The 3000 independent, intrastate laboratories and the nearly 2600 non-JCAH accredited hospital-based laboratories which receive reim-

bursement under the Medicare or Medicaid programs are inspected and certified by State authorities as being in compliance with Medicare standards. Although the Secretary, under the law, is to determine that a State is able and willing to undertake the inspection and certification activities prior to granting such authority, all fifty States act as the Secretary's agent in certifying laboratories and no State has had its authority denied or rescinded. In view of the evidence of fraudulent activities and lack of quality performance discussed later in this report, current inspection and certification activities on the part of the States cannot be said to be universally adequate; monitoring of State programs on the part of the Department of Health, Education, and Welfare clearly has been insufficient.

The nearly 5000 intrastate laboratories which do not receive reimbursement under Medicaid or Medicare and the 50,000 to 80,000 laboratories located in physicians' offices are subject to no Federal requirements of any kind and little is known about the types and volume of procedures performed in such laboratories, although a small percentage of both types of laboratories participate in voluntary proficiency testing programs. Some of these laboratories are also subject to regulation under State laws, but, as noted below, only a handful of States have enacted effective statutes with respect to clinical laboratory regulation.

State Regulation

Several States have responded to the need for regulatory action with respect to clinical laboratories with varying degrees of success. Prior to the enactment of Medicare legislation, New York and California initiated programs whereby the quality of laboratory performance has improved significantly. In addition, New Jersey, Pennsylvania and Kentucky have enacted significant clinical laboratory legislation. Most States, however, have not mounted programs that are comparable to the CLIA '67 program. Some States prohibit advertising by out of State laboratories; others require State licensure for interstate laboratories located outside of the licensing State as a prerequisite to doing business within the State. At the present time, twenty six States have no mandatory program applicable to laboratory performance, and only five States have developed comprehensive programs which require laboratories to adopt internal quality control programs, employ personnel meeting prescribed educational and experience prerequisites, successfully participate in proficiency testing programs, and properly maintain facilities, instruments, and records.

Inconsistency of the Federal effort within HEW

Responsibility at the Federal level for clinical laboratory regulation is severely fragmented. The Center for Disease Control (CDC) of the U.S. Public Health Service is responsible for implementation of the interstate laboratory program under CLIA '67. The Bureau of Health Insurance (BHI) of the Social Security Administration is responsible for the regulation of laboratories receiving reimbursement under Medicare. The fragmentation is compounded by the fact that CDC, which is located in Atlanta, is under the authority of the Assistant Secretary for Health while BHI, which is located in Washington, is responsible to the Assistant Secretary for Human Development.

When CLIA '67 was enacted, it was recognized that its authorities overlapped with those of Medicare, but it was assumed that the activities of the two programs could be readily coordinated. It was not then apparent that two quite dissimilar philosophies of regulation had been established and that any efforts to coordinate the two programs would be seriously hampered by their location in two separate agencies. As noted earlier in this report, interstate laboratories are subject to regulation under both CLIA '67 authority and under the Medicare program, and, until only recently, were inspected by both CDC inspectors and by State certifying authorities.

The Department of Health, Education, and Welfare has been slow to act in coordinating the two programs. In September 1975, only after legislation similar to the reported bill had been introduced in the Senate and less than one week before Senate hearings on the legislation (and nearly nine years after the enactment of CLIA '67), an interagency agreement signed by BHI, CDC, and the Bureau of Quality Assurance (BQA) of the Health Services Administration was produced. The three agencies agreed to consolidate the setting of standards and regulations of both Medicare and CLIA, and to administer the merged programs through the present Medicare certification system. BHI would administer the regulatory functions of both Medicare and CLIA programs through State agencies, and BQA would continue to provide assistance to BHI and coordinate working relationships with other agencies. CDC would develop scientific and technical information to be used to improve laboratories through uniform standards and would monitor the State regulatory programs.

Six months ago, when the House Subcommittee on Health and the Environment held hearings on the predecessor to the proposed legislation, the interagency agreement was not yet a working arrangement although the Subcommittee was advised by Dr. David Sencer, Director of the Center for Disease Control, that he did not "anticipate that it should be too much longer."

Despite the interagency agreement, there is no effective working arrangement among the various agencies respecting coordination of the Medicare/Medicaid and the interstate lab program. There has been no formal delegation of authority under the so-called agreement despite its existence for one year. There has been no agreement among the agencies with respect to such major decisions as the content of personnel standards and quality control standards. In the view of the committee, the chances of an effective interagency agreement between three disparate agencies is virtually nil.

QUALITY OF LABORATORY SERVICES

Because the accuracy of tests performed by clinical laboratories is essential to proper patient treatment, the quality of laboratory services has long been of concern to many individuals and organizations within the health care system. In the mid-1960's, it became apparent that the system which supplied laboratory information to health professionals was, at least in part, seriously compromised by a lack of quality control, by technical incompetence, and by fraudulent practices. Testimony presented at Congressional hearings between 1965 and 1967 (which provided the basis for the enactment of CLIA '67) indicated

that as many as 75 percent of clinical laboratory procedures were performed incorrectly and that more than 60 percent of the tests in selected samples were inaccurate. In addition, it was found that quality varied—among disciplines within individual laboratories, among laboratories within a State, and among laboratories in different States. A host of factors were found to contribute to substandard quality and to variability in quality, including the use of inadequate or inappropriate procedures, equipment, reagents and diagnostic kits; poorly trained personnel; inadequate internal quality control mechanisms; and errors in interpreting or transcribing test results.

Clearly, CLIA '67 has had a positive impact on the quality of laboratory testing in this country's interstate laboratories. In fact, comparison of the results of testing in laboratories subject to the relatively stringent Federal standards under CLIA with those subject to lesser Federal or State requirements, or those subject to no standards at all, demonstrates the positive effects of regulation on accuracy. A National Bureau of Standards study published in 1973 determined that 7.6 percent of microbiology tests and procedures performed in interstate laboratories were in error; other large laboratories had an error rate of 16.7 percent. According to the same study, 26 percent of the sample tests performed by Medicare and Medicaid certified laboratories were inaccurate. Unsatisfactory performance has been demonstrated by 10 to 40 percent of all laboratories in bacteriological testing: by 30 to 50 percent in various simple clinical chemistry tests; by 12 to 18 percent in blood groupings and typing; by 20 to 30 percent in hemoglobin measurements; and by 20 to 25 percent in measurement of serum electrolytes.

In a second study, conducted over the ten year period from 1964 to 1973, the New Jersey Health Department rechecked 35,000 laboratory tests performed by 225 intrastate laboratories. Only twenty of these laboratories showed acceptable results more than 90 percent of the time, and only half of the laboratories showed acceptable results 75 percent of the time.

Nationally, the Center for Disease Control estimates that 15 percent of all laboratory test results are in error. While this figure represents a substantial improvement over the figure of 60 percent in 1967, it still represents in intolerable margin of error.

These appalling statistics, together with litigation which details the severe consequences of misdiagnosis resulting from faulty laboratory tests provide ample evidence of the critical need for reform. For example, due to an incorrect bilirubin reading an RH negative baby was not transfused. Tragically, that baby is now severely mentally retarded. *Schnelby* v. *Baker*, 217 NW 2d (Iowa 1974). In another instance, a diabetic patient died when a doctor relied on a faulty blood sugar test result and prescribed the wrong medication. *Kinel* v. *Hycel, Inc.*, Ill. City Circuit Court, No. 70 L241, 1973. A case of controllable cancer spread as a result of delay in treatment due to an erroneous Pap smear result. *Cornell* v. *Clinical Labs*, Cal. Super. Ct., Los Angeles City, Docket No. NCC 4792, June 29, 1971.

Clearly, lack of even and effective regulation of clinical laboratories has resulted in a situation in which the American public cannot have confidence in clinical laboratory testing, despite its critical relationship to good health.

EXPERIENCE UNDER THE MEDICAID AND MEDICARE PROGRAMS: FRAUD AND ABUSE

The Medicare and Medicaid programs, titles XVIII and XIX of the Social Security Act, provide coverage for laboratory services. Payments under the programs for laboratory tests are made in three ways: they are included as part of payment for hospital services, as part of payments for phisician services, or are made directly for independent laboratory services. For independent laboratory services alone, estimated expenditures under the two programs were $213 million in FY 1976. Approximately $180 million of this total was expended through the Medicaid program (and this amount may be significantly underreported by the States to the Federal government). While it is impossible to know how much is spent for laboratory services which are included as charges or costs in physicians' and hospital bills, it is clear that the amount expended by the two programs is substantial, and almost certainly in excess of $1 billion annually.

Increases in expenditures for laboratory services under the two programs have been dramatic. The increase in Medicaid expenditures has been at least 15 percent a year, and in some areas—like New York City—the increase has been more rapid. The Committee received testimony that the increase in New York City Medicaid payments for laboratory services over the past 5 years has been an astonishing 300 percent. This increase occurred at a time when there had been a decrease in the number of persons eligible for Medicaid. These kinds of increases are occurring because of a combination of factors: no effective control on prices, overutilization of tests, fraudulent claims, and general abuse of the benefit, primarily by the provider.

Over the past several years, there has been increasing concern with respect to the potential for fraud and abuse among clinical laboratories participating in Medicaid and the lack of effective fiscal controls. One evidence of this concern has been the attention focused on the issue by State commissions and legislative investigative committees. Major investigations have been conducted in New Jersey and New York.

Testimony presented to the Committee by the Executive Director of the New Jersey State Commission of Investigation provided evidence of the seriousness of the situation. The Commission found that physicians often determined which laboratories would do the test work for their Medicaid patients by the amount of the kickbacks and rebates offered by the laboratory. Testimony before the Committee's Subcommittee on Oversight and Investigations indicated that these kickbacks commonly run around 25 percent. Physicians, of course, did not inspect the work premises of the laboratories which were doing the business for them. The Commission found instances where work was carried on in converted garages or basements where even minimum sanitary and test quality standards could not be met. Often the laboratory where the physician sent the tests never did the test work—they would in turn send it on to another laboratory facility. At each stage in the process, there was a mark-up on the charge for the test performed. New Jersey found it could reduce its fee schedule for laboratory tests by 40 percent, without harmful effects if it eliminated the

excess amounts built into the fee which encouraged high mark-ups and kick-back arrangements.

A recent investigation by the Subcommittee on Long-Term Care of the Senate Special Committee on Aging documented similar instances of substantial and widespread fraud and abuse among clinical laboratories providing services under Medicaid and Medicare. Although the investigation was centered in Illinois, the Subcommitte received considerable evidence from other States showing similar patterns of questionable and outright fraudulent practices.

While the Senate Subcommittee noted that the full extent of fraud with respect to clinical labs is unknown, it concluded as a result of its investigation that at least $45 million of the $213 million in Medicare and Medicaid payments for clinical laboratories is either for fraudulent or unnecessary services. This represents almost $1 out of every $5 spent for such services.

While the actual numbers of offenders identified in the investigations were small, their proportion of the public funds for lab services was substantial. In New York, 16 clinical laboratories controlled 70 percent of the Medicaid business. In New Jersey 12 clinics controlled more than 60%, while in Illinois 21 labs controlled over 80%. The Senate Subcommittee investigation confirmed the New Jersey State Commission finding that kickbacks are so prevalent that laboratories refusing to make them are practically unable to secure the business of physicians or clinics treating Medicaid patients.

Kickbacks take a number of forms including cash, long-term credit arrangements, gifts, supplies and equipment, and the furnishing of business machines. The most common practice, however, involves the "rental" of a small office space in a medical clinic for amounts which are far in excess of the reasonable value of the space. Frequently, the "rent" is determined by paying a percent of the business sent to the laboratory, often in amounts as high as 30 to 45 percent of the Medicaid billings of the physician or clinic sent to the laboratory. In one case reported by the Senate Subcommittee, laboratory representatives indicated that they would need to "rent" enough square feet in a clinic to house a blood drawer, a chair and a cabinet. The total rent for the clinic space was $450 a month, but the laboratory proposed to pay rents in the amount of $5,000 or $6,000 a month—depending on the volume of tests—for this tiny space in the clinic. All investigations conducted and testimony received by the Subcommittee on Health and the Environment of this Committee and the other Congressional Committees indicate that these practices are not uncommon.

There is also substantial evidence of abuse in pricing practices. Excessive charges for laboratory services was the subject of a report issued by the General Accounting Office on August 4, 1976. This report, entitled "Tighter Controls Needed Over Payments for Laboratory Services Under Medicare and Medicaid", concluded that Medicare and Medicaid often pay substantially more for laboratory services than the prices charged by independent laboratories. In some cases, physicians obtain the services from independent laboratories for reasonable prices but receive program payments which include large mark-ups. GAO examined billings and payments records for 155 independent laboratory services covered by Medicare obtained by

physicians or physician groups in Florida, Georgia, California, and Arizona. For these services, physicians paid the independent laboratories $776 for services billed to Medicare at $1,950. The markups allowed for payment totaled $1,013 or 131% more than was charged by the laboratories. Instances were cited of 400% mark-ups. In the metropolitan Washington, D.C. area, Medicaid fees generally exceeded the highest lab prices charged to private payors for the same services. The largest differential was in Virginia where the Medicaid fee of $79 for nine procedures exceeded the highest independent laboratory price to private payors of $42.75 by $36.25, or 85%.

The Senate Subcommittee on Long-Term Care of the Special Committee on Aging documented that high mark-ups by physicians were not the only pricing problem. Often, independent laboratories charged substantially higher rates to the public programs, maintaining double price lists—one for charges to private patients, one for charges to the Medicaid program. The prices charged to Medicaid generally ranged from twice as much to five times as much. These kinds of excessive charges make possible the payment of substantial amounts in kickbacks, while still allowing the laboratory excessive profits.

The Committee has also received testimony that it is not uncommon for independent laboratories to send work on to other laboratories—sometimes large, automated laboratories, even State-run laboratories, who do the tests at low cost—and then the original laboratory, which has served only as a middle man, charges high rates for its "services," either to the physician (who may then add on another mark-up himself) or the Medicaid program.

In summary, the Committee has determined that:

(1) there was a great deal of abuse in pricing practices for laboratory services paid for by public programs;

(2) that kickbacks and other fraudulent practices were not uncommon, and that prosecutions and penalties under current law were insufficient to stop them;

(3) that percentage rental arrangements clearly unrelated to the reasonable value of the space rented were only more sophisticated forms of kickback, and resulted in increased costs to the program;

(4) that Medicaid payments commonly went to laboratories, either directly or indirectly, that failed to meet minimal standards, and

(5) that it was often close to administratively impossible for States to exercise appropriate surveillance over provision of and use of all laboratory tests under the current arrangements for securing and paying for these services.

Committee Proposal

CONSOLIDATION OF REGULATION OF CLINICAL LABORATORIES

Extension of the scope of the Clinical Laboratory Improvement Act of 1967.

As noted above, the Clinical Laboratory Improvement Act of 1967 extends only to laboratories engaged in interstate commerce. Under the terms of the reported bill ("CLIA 76") the coverage of the pro-

visions of CLIA would be extended considerably. First, it would extend to all "independent" laboratories (i.e., laboratories not located in a hospital) which are in interstate commerce whether or not they receive Federal funds under the Medicare and Medicaid programs. Secondly, this bill will for the first time extend meaningful regulation to intrastate hospital-based laboratories. As noted above, under existing Medicare law hospitals which are certified by the Joint Committee on Accreditation of Hospitals (JCAH) are exempt from the requirements of that law. Unquestionably, standards promulgated under the reported bill will be of a more stringent nature than those presently in existence under the JCAH program. Thus, the provisions of the Committee's bill promise to have a substantial effect on the quality of laboratory services performed in this nation's hospitals. Finally, under existing Medicare standards, as well as existing law under the Clinical Laboratory Improvement Act of 1967, all laboratories owned and operated by physicians and other health professionals—no matter how large—are wholly exempt from Federal standards. As noted in more detail below, this exemption has been limited to laboratories in which the only tests performed are tests performed by the health practitioners themselves or to laboratories of not more than five practitioners in which such practitioners perform all the tests in the laboratory or in which persons under their employ perform only routine tests. Thus, large physician labs and laboratories in which persons employed by physicians and other health practitioners perform non-routine tests will, under this bill, for the first time be required to demonstrate the quality expected of interstate laboratories.

Standards Governing Laboratories Subject to CLIA '76

Under the provisions of the reported bill, all clinical laboratories within the scope of the legislation will be subject to national standards. Standards prescribed in the bill may be grouped into four categories. First, laboratories subject to the standards will be required to maintain appropriate quality control programs. Secondly, such laboratories will be required to maintain such records, equipment, and facilities as may be necessary for proper and effective operation. Third, standards must include requirements for periodic proficiency testing of laboratories. Finally, standards must prescribe qualifications for the personnel who direct, supervise, or who are employed by such laboratories.

In the Committee's view, the guidelines in the legislation relating to standards will insure accurate laboratory tests and procedures, while at the same time authorize the flexibility necessary in order that variations in the types of tests and procedures performed by the laboratories may be taken into account and so that career mobility within clinical laboratories remains possible.

Thus, the reported bill specifically authorizes national standards for clinical laboratories to vary on the basis of the type of tests, procedures, or services performed by such laboratories or the purposes for which such tests, procedures, or services are performed. For example, the type of training or experience required of the director of a laboratory may appropriately vary depending upon the types of tests performed in the laboratory. In addition, a laboratory in which sophisticated research is being conducted, but in which only routine tests

to determine the course of treatment of a patient are conducted, may well be directed by a person with qualifications different from those of a person who directs a full service, commercially-oriented laboratory. Moreover, the Secretary may determine that quality control programs should vary according to the types of tests performed by the laboratory.

In addition, the personnel qualifications required of laboratories subject to the reported bill are intentionally structured so that qualifications for such personnel will include options. For example, qualifications for directors of laboratories may include licensure, training, or experience requirements or any combination of such requirements. Qualifications for supervisors must require such personnel to meet experience requirements and either to meet training requirements or successfully complete proficiency examinations developed by the Secretary. Qualifications for technologists employed in laboratories must require technologists to meet experience requirements, training requirements, or successfully complete proficiency examinations. It is with this latter group of personnel—technologists—that the Committee is most concerned. What the Committee wishes to avoid, consistent with quality and accuracy, is the establishment of a "guild system" whereby only persons with rigid academic credentials would be able to be employed in this nation's clinical laboratories. Instead, it is the Committee's view that persons without such requirements should be able to be employed as technologists if their experience or completion of proficiency examinations demonstrate them to be competent.

Phasing in of National Standards

The Committee recognizes that laboratories which for the first time will become subject to national standards will require some time in order to comply with them. For this reason, the legislation provides for a phase-in period for clinical laboratories, with special consideration being given to rural hospital laboratories.

First, clinical laboratories engaged in interstate commerce will be required to continue to be subject to regulation under the Clinical Laboratory Improvement Act of 1967 and laboratories subject to regulation under Medicare and Medicaid will continue to be so subject until the standards are changed through application of the reported bill.

Laboratories not subject to Medicare or Medicaid regulations, or which are not engaged in interstate commerce, will not be required to comply with national standards until two years following the date that national standards become effective (which must be one year following the date of enactment of the bill), or three years from the date of enactment.

Laboratories which receive reimbursement under the Medicare or Medicaid programs will likewise become subject to national standards promulgated under the provisions of CLIA '76 three years following its enactment. Clinical laboratories located in rural areas in which individuals with the qualifications required for supervisory personnel or for technologists employed by the laboratory (or both) are not available, which perform services solely for hospitals and health practitioners located within such rural area, and which pro-

vide the Secretary satisfactory assurances that they will take such actions as may be necessary to train individuals to meet such qualifications or to employ such individuals with such qualifications receive an additional two year exemption from compliance with standards relating to such personnel. Thus, in the Committee's view, a reasonable period of time has been authorized in the reported bill for laboratories to prepare themselves for increased regulation. Owners and operators of laboratories will know well in advance of requirements applicable to them and should not anticipate delays beyond those authorized by this legislation.

Exemption from National Standards

In the Committee's view, there are limited situations in which, because of the nature of a clinical laboratory, national standards should not apply to it. Thus, exceptions are made in the legislation for three types of laboratories: research laboratories, insurance laboratories, and certain laboratories located in the offices of physicians and other health care professionals. First, the legislation requires that upon application, the Secretary exempt from national standards any laboratory in which the only tests or procedures which are performed are tests or procedures for research. This exemption is, however, limited to laboratories which perform research other than research to determine the course of treatment for a patient.

Secondly, the legislation contains an exemption from national standards for clinical laboratories in which the only tests or procedures performed are tests or procedures for persons engaged in the business of insurance for the purpose of determining whether to write an insurance contract or determining eligibility for payments under an insurance contract. Since such laboratories have nothing to do with health care, the Committee has chosen to continue the exemption for such laboratories.

Third, certain laboratories owned and operated by physicians, dentists, or podiatrists are exempt-or eligible for exemption-from national standards. National standards do not apply to clinical laboratories which are located in the office of, and operated by, a licensed physician, dentist, or podiatrist (or a group of such practitioners) in which the only tests or procedures which are performed in the laboratory are tests or procedures performed by such practitioners in connection with the treatment of their own patients. Secondly, the Secretary is required, upon application, to exempt from national standards any clinical laboratory (1) which is located in the office of, and operated by, a licensed physician, dentist or podiatrist or a group of not more than five such practitioners, (2) in which the only tests or procedures performed in the laboratory are tests or procedures performed solely in conjunction with the treatment of the patient of such practitioners, and (3) in which the only tests or procedures performed in the laboratory are performed by the practitioners who own or operate the laboratory and routine tests (performed either by the practitioners themselves or personnel who are not physicians, dentists or podiatrists) or only such routine tests or procedures. The application for exemption is required to include information concerning the number and type of tests and procedures conducted in the laboratory, qualifications of personnel who participate in the conduct of tests or procedures or the

collection and transmission of specimens, the quantity and type of tests and procedures conducted by such personnel, the type of proficiency testing (if any) participated in by such personnel, the scores received in any such testing, and a description of the quality control programs in effect in such laboratories.

A summary of the information contained in the applications for exemption of such laboratories is required to be submitted by the Secretary, to the Congress. Further, on the basis of the information contained in the application for exemption, the Secretary is required to make recommendations to the Congress as to whether clinical laboratories granted such exemptions should be required, as a condition to their continued exemption, to have laboratory procedure manuals, participate in laboratory proficiency testing programs, and maintain quality control programs. This information and report, which the Committee considers critical to an understanding of the quality of procedures and tests performed in laboratories located in physicians offices, will be used by the Committee in making future judgments concerning whether exemptions for physicians offices should be continued.

The Achievement of Primary Enforcement Responsibility by States

The Committee is well aware that several States have adopted standards for clinical laboratories which are comparable to standrds required under the existing provisions of the Clinicl Laboratory Improvement Act. In the Committee's views, it is wholly appropriate—and indeed desirable—for States that have adopted standards comparable to or more stringent than national standards to implement such standards without Federal interference. For this reason, the reported bill authorizes States to assume primary enforcement responsibility for the purpose of regulating the quality of clinical laboratories in their jurisdiction. Thus, the reported bill requires the Secretary to designate, upon application, a State as having primary enforcement responsibility if the Secretary makes six determinations: (1) that the State has adopted standards applicable to clinical laboratories which are no less stringent than national standards and a system for the licensure of laboratories comparable to a system required under national standards, (2) that it has adopted and is implementing adequate procedures for the enforcement of such standards, (3) that it will keep such records and reports with respect to licensing and enforcement as the Secretary may require, (4) if it permits exemptions from its requirements, that it permits them under conditions no less stringent than those applicable under CLIA '76, (5) that it has adopted and can implement adequate procedures for control of health hazards resulting from clinical laboratories, and (6) that it has designated a single agency to enforce its standards and administer its licensure system. If a State has achieved primary enforcement responsibility, it is then authorized to regulate all intrastate labs located within it, as well as interstate laboratories so located or doing business pursuant to agreement with the Secretary. A limited exception is made for certain Federal laboratories.

In addition, the proposed legislation contains authorizations of appropriations of $3.75 million dollars per year to be made available to States which have achieved primary enforcement responsibility

for the purpose of assisting them in regulation of clinical laboratories. This authorization, the amount of which is predicated on the costs of enforcing standards applicable to non-Medicare and Medicaid laboratories, but which need not be utilized by States solely for such purpose, complements existing authority whereby State agencies are reimbursed by the Department of Health, Education, and Welfare from monies available from the Social Security Trust Fund for the purposes of implementing the existing Medicare standards. Such funds would continue to be made available to States.

Use of Non-Governmental Entities to Assist in Implementation of Standards

Several national professional organizations have, over the years, developed self-enforcement procedures for the regulation of clinical laboratories. These organizations include the College of American Pathologists, the Joint Commission on Accreditation of Hospitals, the American Society of Internal Medicine, and others. Under CLIA '67, laboratories accredited by such national organizations are exempt from Federal regulations if the standards applied by such organizations are equal to or more stringent than the requirements of that Act. Under existing law, the College of American Pathologists has been accepted as an entity with standards equal to or more stringent than the provisions of Federal standards applicable to interstate laboratories. In the Committee's judgment, it is appropriate to continue the authority for such arrangements. Thus, the legislation authorizes the Secretary and any State which has primary enforcement responsibility for the regulation of clinical laboratories to enter into agreements with qualified public or non-profit private entities which have adopted standards at least as stringent as Federal or applicable State standards under which such entities (1) make such inspections as the Secretary or State may require to assure compliance with standards, (2) administer such proficiency tests and periodic examinations as the Secretary or the State may require for clinical laboratories and their personnel, or (3) do both.

Sanctions Applicable to Laboratories Which do not Comply With the Provisions of the Bill

The reported bill imposes severe sanctions for violation of the national standards. It provides that any person who solicits or accepts, directly or indirectly, any specimen for a laboratory test or other laboratory procedure which is required to have in effect a license and which does not have such a license or which is not authorized by its license to perform such test or procedure shall be fined not more than $10,000 or imprisoned for not more than one year, or both. In addition, the reported bill provides that no clinical laboratory which is required to have in effect a license issued by the Secretary and which does not have such a license may receive a grant, contract or other form of financial assistance under the Public Health Service Act, or charge or collect for laboratory services for any entity which receives a grant, contract or other form of financial assistance under such Act. In addition, the charges of such a laboratory may not be included in determining Federal payments under the Medicare or Medicaid programs.

Implementation of CLIA '76 by HEW

Fragmentation of efforts within the Department of Health, Education, and Welfare with respect to regulation of the quality of clinical laboratories cannot be allowed to continue, particularly in light of the vastly expanded authority of the Department under the proposed legislation. It is the Committee's position that the allegiance of persons within the Bureau of Health Insurance and the Center for Disease Control to different Assistant Secretaries of HEW is the principal reason for the inability of these agencies to achieve accord on a division of responsibility and agreement on national policy. What is needed, in the Committee's view, is a clear expression by Congress of the need for a coordinated effort.

Thus, the Committee has taken the unusual step of requiring the establishment of an identifiable administrative unit, within the Department of Health, Education, and Welfare, which is responsible for coordination of the regulatory efforts authorized by the Public Service Act and the Social Security Act. This unit must, under the reported bill, be under the direct supervision of the Assistant Secretary for Health.

The implementation of the Clinical Laboratory Improvement Act of 1976 will be difficult at best. There can be no room for two or more agencies feuding over responsibilities and content of regulations. The responsibility for implementation of the Act should be clearly fixed and one organization in HEW should be designated and given the responsibility for all clinical laboratory matters. This agency must have technical and administrative competence in working with State health agencies, other Federal agencies and professional organizations. Experience in the development of workable standards which could be adopted by the various States to assure consistent performance by all clinical laboratories of accurate laboratory procedures and services is, in the Committee's view, essential to implementation of a successful program.

Examination of those agencies within HEW who are involved with regulation of clinical laboratories indicates that the Center for Disease Control is competent to implement the provisions of H.R. 14319. CDC has an established relationship with State laboratory agencies, a factor critical to the future success of the program. Information gained from implementation of CLIA 1967 will be an invaluable tool.

CDC has a broad technical capability and many years of clinical laboratory experience, which will be critical to the development of a national laboratory licensing program. No other government agency has the experience, reputation, and traditions in all of the disciplines of clinical laboratory medicine needed to administer the program that is called for under the reported bill. Therefore, it is the view of the Committee that the Secretary should designate the Center for Disease Control as the agency responsible for the implementation of the Clinical Laboratory Improvement Act of 1976.

PROVISIONS WITH RESPECT TO FRAUD AND ABUSE

Increased Penalties for Fraud

The Committee proposal would increase the penalties under the Medicare and Medicaid programs for making or taking bribes, kick-

backs, fraudulent claims, and other similar actions from misdemeanors to felonies, and by increasing the maximum penalty from $10,000 and one year in prison to $10,000 and 3 years in prison.

There have been reports that Federal and State attorneys have been reluctant to prosecute cases of fraud under Medicare and Medicaid because they were not felonies; the Committee proposal is designed to respond to that deficiency in current law.

Employee Protection

Further, the reported bill contains a provision which would protect employees who intend to testify or have testified against laboratories subject to the standards of the bill, or who have supplied information necessary to enforcement proceedings, or otherwise assisted or participated in such a proceeding. Employees who believe they were discharged or discriminated against because of these activities could file a petition with the Secretary of Labor within 30 days of the action, and, if, after a full investigation, the complaint is founded and a settlement cannot be reached, the Secretary is to issue an order providing relief to the employee. The Committee believes this kind of protection will lead to more effective enforcement of the laboratory standards and will assist in the successful prosecution of fraudulent cases.

Bribes

Further, the reported bill would clarify the legislative provisions of Medicare and Medicaid to indicate that bribes need not be in the form of money to qualify for prosecution under the law. Cars, furniture, vacations, and other similar things of value would constitute bribery just as clearly as the direct payment of money, and the proposed legislation amends the law to so indicate.

Discriminatory Billing Practices

The Committee proposal would make the practice of higher charges to public financing programs (Medicare, Medicaid and the Maternal and Child Health program) for services than are charged to others grounds for loss of a laboratory's license, or ineligibility for application for a license for up to two years, or both. In recognition of the fact that delays in payments under public programs may necessitate a slight increase in administrative costs the committee proposal provides that such costs would not be considered discriminatory billing of public programs, but only to the extent that it clearly could be established that a differential in administrative costs exists.

Similarly, the reported bill would add a corresponding provision to title XIX. Under Medicare, Medicaid, and Maternal and Child Health programs, laboratory services are reimbursed on the basis of prevailing charges in the locality for comparable services under comparable circumstances. Investigations of the laboratory industry have uncovered many practices which artificially increase the prevailing charges for laboratory services. The Committee bill would establish reimbursement principles which would provide limits for payments to individual laboratories for services based on purchasing practices which a prudent buyer would observe. To achieve this goal the Committee bill would specifically limit reimbursement under title XIX for laboratory services to the lowest rates charged by the laboratory.

A reasonable billing period, to be determined by the Secretary, could serve as a basis for establishment of the lowest charge.

The Committee would note that, in addition to this requirement, the Secretary would retain authority to apply to Medicaid payments the limits on prevailing charge levels included in Medicare under Section 1842(b)(3) of the Social Security Act, (referred to under Medicaid in Section 1903 (i)(1)). Medicaid locality designations may be established by the Secretary on a national, state or local basis, under the provisions of Section 1842(b)(3). Further, in those cases where the Secretary has determined that laboratory services do not generally vary significantly in quality from one laboratory to another the charge determined to be reasonable may not exceed the lowest charge at which laboratory services are widely and consistently available in a locality.

The reported bill would provide States with the authority to limit the amount paid to a laboratory or physician for services performed under subcontract by another laboratory to the lowest amount charged by the original billing party (which in turn must be at the lowest rate which that party charges any payor for such tests). In the case of the physician, the State could allow a nominal charge by the physician for his professional services provided in conjunction with the test. Such a mark-up by the physician could be included for payment only at the option of the State (which could establish a payment system for laboratory services which makes no allowance for a physician mark-up), and even then, only if it is nominal and meets standards of reasonableness, as determined by the Secretary. In this regard, the Committee would note that the General Accounting Office recently urged the Department to establish such standards for Medicare payments; if developed, the Committee would expect that they would operate as a ceiling on mark-ups allowed under Medicare as well. Physician providers of laboratory services, whether they perform the laboratory services or employ others to perform laboratory services, would be subject to the lowest charge limitations of laboratories in the medical service locality, as designated by the Secretary.

Percentage Arrangements

The reported bill would prohibit the use of any Federal funds to pay any portion of a reimbursement amount for laboratory services which incur because of a commission or finder's fee, or because of a rental arrangement which is based on a percentage of business or is otherwise clearly unrelated to the fair value of the space being rented. The Committee believes that these kinds of percentage lease arrangements, particularly in clinics or physicians' offices, are primarily utilized as simply a more sophisticated form of kickback. While not reducing in any way the authority to prosecute these kinds of practices under the felony provisions of the bill, this Committee proposal is designed to provide more leeway in stopping the practice even where a kickback cannot formally be proved.

Laboratory services provided in hospitals for persons receiving inpatient or outpatient services in that facility are exempt from this limitation. The Committee also intends that the exemption apply in situations in which the vast majority of laboratory services for patients

of a hospital are performed in the hospital laboratory, but, because of the sophisticated nature of a limited number of tests or in emergency situations, some procedures are performed by a clinical laboratory independent of the hospital which is directed by the same person or professional group that directs the hospital-based laboratory. The Committee felt that sufficient information on the use of rental arrangements of hospital laboratory space was not available to assure that banning percentage rental arrangements in the hospital setting was appropriate. Thus, the Committee proposal directs that a study be undertaken to examine this arrangement and all other arrangements between hospitals and providers for the provision of clinical laboratory services, including salaries, fees based on percentages, and similar financial arrangements with pathologists. The Committee believes that information on this subject is already available in scattered sources, and therefore provides for the completion of the study by the Department within six months of enactment of the legislation so that any legislative action found to be necessary can be undertaken early in the next Congress.

Submission of certain information to the Secretary and to Health Systems Agencies.

The reported bill also contains provisions whereby the Secretary and health systems agencies will, for the first time, be made fully aware of the terms of contracts between physicians and clinical laboratories and the charges that laboratories make to physicians, in order that an evaluation may be made of the appropriateness of the terms of the contracts and the differences between charges made to patients for clinical laboratory services and the charges that laboratories made to physicians who ordered the tests for such patients. It requires that, in order for a clinical laboratory to be eligible for issuance or renewal of a license, it must submit with its application for such issuance or renewal to the Secretary and to the health systems agencies serving the area in which the applicant is located (1) a schedule of fees the applicant charges for the laboratory services it provides and (2) such information which may be necessary to disclose any contractual relationships in effect between the applicant and physicians and other health professional respecting the laboratories services and the terms of any contracts between the applicant and such persons. Appropriate confidentially requirements are included with respect to this information. However, within the confines of the confidentially protections of the bill and those of the Freedom of Information Act, this information will be very useful to the Secretary in determining whether contracts between physicians and clinical laboratories for payment of services under programs in which the Federal government is responsible for reimbursement is reasonable and fair.

In addition, health systems agencies will be able to make generally available information concerning fee schedules so that consumers may compare the charges that laboratories make to physicians who order tests and the charges the physicians make to such consumers. Also, such information will be useful to Federal and State law enforcement officials in the enforcement of the provisions of the bill or of other Federal or State criminal laws.

Freedom of Choice

During its deliberations, the Committee became convinced that there were serious deficiencies in the design of the Medicaid program in terms of the provision of laboratory services. The Committee was impressed by testimony that the number of providers involved—particularly in large urban centers where so called "Medicaid mills" were prevalent, and where bills came through clinics or physicians who dealt with other large urban centers were so-called "Medicaid mills" were prevalent, policing of quality standards and charging practices nearly impossible. The Committee was impressed with the proposals put forth by representatives of New Jersey and New York City for alternate arrangements for the purchase of laboratory services. The Committee was not convinced by the argument that it should not permit Medicaid administrators to implement systems which provide promise of better quality and lower prices simply because such a system would deny Medicaid patients the opportunity to enjoy "freedom of choice" of their provider of laboratory services. The Committee did not believe that freedom of choice was a reasonable concept in the context of laboratory services where the physician, not the patient, determines who will perform the laboratory tests.

The reported bill contains a provision which would allow States (or parts thereof) to purchase laboratory services under arrangements which would not be subject to the general freedom of choice requirements of the Medicaid law, provided that the Secretary of Health, Education, and Welfare approved the plan. The Secretary would determine that services would be purchased only from laboratories that met standards, and that the prices charged the program would not exceed the lowest amount charged to others for similar tests, or, if the purchasing arrangements were agreed to on some unit price basis, that the aggregate expenditures would not exceed the aggregate expenditures that would have been anticipated if each test was charged at the lowest rate charged to others for that test. Most importantly, the Secretary must be satisfied that under the arrangement adequate laboratory services would be available to the physicians and other providers treating Medicaid patients, and the Committee expects that he would approve State plans only when this condition is met.

It is the view of this Committee that, because this legislation authorizes an override of the Medicaid freedom of choice provision with respect to laboratory services, it will probably result in a reduction in the number of providers from whom a State, or political subdivision, purchases such services. In fact, it would be possible for States, or political subdivisions, under this Act to enter into arrangements with only one provider of laboratory services in an area. The Committee's intent, however, is not to encourage such a monopolistic situation in any large health care delivery area. Obviously, in such an area it is desirable to encourage the utilization of several providers to the extent that this is compatible with the availability of adequate and low-cost services. If only one provider is serving a very large population group, the State could become the "captive" of the provider and find it administratively difficult to switch to another provider should the first prove to be inadequate or found to be charging excessive rates. In addition, accessibility of the services to the physician should

be a consideration in determining the number of such arrangements. Therefore, it is the Committee's intent that States making arrangements with providers of laboratory services under this legislation should generally not make such arrangements with only one provider of such services in any large health care delivery area. Furthermore, the Secretary in establishing policies and rules to implement this provision should discourage such monopolistic situations in consideration of the implementation.

Further, it is the view of the Committee that States may find it beneficial to make arrangement for the purchase of services only with laboratories that provide services to both private and public patients. In many cases providers of laboratory services may have established quality assurance mechanisms and fee schedules for their services, thus providing the purchaser with a ready means of determining the lowest rate charged for quality services. Even where providers have not taken these steps, experience has shown that the existence of a private clientele has a quality assurance effect on the services provided to public patients. In addition, it is the intent of the Committee to discourage the development of a two class system of health care in this country by discouraging States from purchasing laboratory services from providers whose only customer is Medicaid. The Secretary, in developing rules and policies for the implementation of these provisions, should take into account the probable beneficial effect of a system of mixed private and public purchasing of the same services.

Program Oversight

The Committee's principal oversight activities with respect to this program have been conducted by the Subcommittee on Health and the Environment in connection with its consideration of the legislative authorities for the program. Legislative hearings on the programs were conducted in March of 1976 and the findings are discussed in the report under Committee Proposal as the proposed legislation is designed to respond to the Subcommittee's findings. Oversight hearings on the problems of Medicaid fraud and abuse, including fraud and abuse in the clinical laboratory industry, were conducted by the Committee's Subcommittee on Oversight and Investigations on February 13, 1976, and information obtained during those hearings was used in the development of the proposed legislation. The Committee has not received oversight findings with respect to this program from the Committee on Government Operations.

Inflation Impact Statement

The Committee anticipates that the enactment of H.R. 14319 will have a significant impact on inflation in the health care field by reducing laboratory charges reimbursed by Medicare and Medicaid programs. Further, the amounts authorized under this legislation which is intended to regulate a nearly $10 billion industry represent a minimal Federal outlay when projected savings to be realized under the legislation are taken into account. As noted below in the report of the Congressional Budget Office, it is anticipated that a net savings of more than $237 million over the next five years is a conservative estimate of the effect this legislation will have on laboratory charges.

Congressional Budget Office Cost Estimate

A cost estimate was requested on H.R. 14319 when it was ordered reported from the Committee on Interstate and Foreign Commerce, and the Congressional Budget Office has provided the following information.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill No.: H.R. 14319.

2. Bill Title: Clinical Laboratory Improvement Act of 1976.

3. Purposes of Bill: To amend the Public Health Service and Social Security Acts in order to assure expanded and improved regulation of clinical laboratories and do reduce the present levels of reimbursement under Medicare and Medicaid for laboratory services. Provisions of the bill that have cost impact include:

(1) Authorization of financial assistance to the states in the form of grants to assist in meeting the costs of administering and enforcing standards applicable to clincial laboratories. (Section 353(m)(4))

(2) Authorization of contract funds to state public health laboratories to assist those laboratories in carrying out "tests to determine the presence and quantity of carcinogenic and other toxic substances in humans." (Section 353(o))

(3) Exclusion, in the determination of reimbusement for clincial laboratory services under Medicare and Medicaid, of costs or charges for a commission or finder's fee or for other costs deemed to be unrelated or disproportionate to the market value for such services, equipment or facilities. (Section 1132)

(4) Elimination, under Title XIX, of the "freedom of choice" provision and the granting of permission to states to make arrangements with selected laboratories for the purchase of laboratory services (e.g. through a competitive billing process, etc.). (Section 1132(b)(1))

4. Cost Estimate:

[In millions of dollars]

	Fiscal year—				
	1977	1978	1979	1980	1981
Authorizations:					
Sec. 353(m)(4)		2.81	3.75	3.75	.94
Sec. 353(o)	1.50	1.50			
Total costs	1.50	4.31	3.75	3.75	.94
Savings:					
Sec. 1132—Exclusion of certain charges	2.1	4.7	5.1	5.7	6.2
Sec. 1132(b)(1)—Elimination of "Freedom of Choice"	13.8	36.3	46.2	58.3	73.2
Total savings	15.9	41.0	51.3	64.0	79.4

5. Basis for estimate: The outlays associated with the authorizations provided for (assuming that the appropriations

levels would equal authorizations) are based on the following spendout rates:

1. Grants to States: 75%, 25%.
2. Contracts with State Laboratories: 50%, 50%.

The savings incurred as a result of the "exclusion of certain charges" provision are based on an assumption that total laboratory reimbursement under Medicare would be $42.5 million in 1977. Officials in both New York and New Jersey estimated that as much as 33 percent of laboratory costs could be attributed to finder's fees and disproportionate costs. However, because of difficulties in fully implementing this provision and the variations throughout the country in laboratory costs, a 10 percent savings was assumed. Also, because of the time necessary in FY 1977 to implement this provision, it was assumed that only half the total savings would be accrued. 1978–1981 savings also assumed the 10 percent savings but inflated by 10 percent a year to account for the overall increase in laboratory services (the 10 percent was based on BLS data for the average annual increase in laboratory costs). Although this provision also applies to Medicaid, it is assumed that the implementation of Section 1132(b)(1) would take into account almost all the savings accrued through this provision and would thus be reflected in that estimate.

To estimate the savings associated with Section 1132(b)(1), the Senate Special Committee on Aging projection on 1976 laboratory service costs of $213 million under Medicare and Medicaid was used as a base. Assuming Medicare account for $37 million of this figure, Medicaid laboratory services cost $176 million or $96.8 million in Federal expenditures (inflating this figure by 15 percent gave a 1977 level of $111.3 million). Estimates of savings associated with this provision were made by three States: New York, New Jersey and California, and were 50 percent, 50 percent and 20 percent, respectively. Because of variations in the present methods and levels of reimbursement for laboratory services from state to state, and assuming different approaches to implementation by the states, an overall savings rate of 25 percent was used for 1977. Also, because of delays associated with full implementation of the program, actual savings for 1977 were assumed to be 50 percent of the total if the program had been in effect for the full year. 1978–1981 savings were calculated by taking the difference between projected laboratory costs under current law (inflated each year by 15 percent) and the projected costs under this provision. Projected costs used the previous year estimate and inflated that by 10 percent per year (the 10 percent assumes the BLS average annual increase). Thus, if projected costs under current law for 1977 were $111.3 million, and $83.5 million under this provision (assuming a 25 percent savings), and inflating the former number by 15 percent and the latter number by 10 percent, the 1978 savings would be $128 million minus $91.7 million—or $36.3 million.

The savings that are estimated under this provision might, in fact, increase over the years because there could be some spin-off of the reductions in Medicaid laboratory reimbursement levels onto the Medicare program as well. It is difficult to assess the impact of this spin-off on total savings and, thus, this estimate should be viewed as a minimum.

Also, there could be an increase in costs associated with this bill if States do not qualify for primary enforcement responsibility. In this case, the federal government would have to assume this function, thus requiring additional staffing and associated costs.

6. Estimate comparison: Not applicable.
7. Previous CBO estimate: None.
8. Estimate prepared by Jeffrey C. Merrill.
9. Estimate approved by James L. Blum, Assistant Director for Budget Analysis.

Agency Reports

Agency reports were requested on H.R. 11341, a similar predecessor to H.R. 14319, on January 21, 1976, from the Office of Management and Budget and the Department of Health, Education, and Welfare, but to date no reports have been received.

MINORITY VIEWS ON H.R. 14319—CLINICAL LABORATORIES IMPROVEMENT ACT OF 1976

The Clinical Laboratories Improvement Act of 1967 has resulted in the licensing by the Federal Government of those approximately 900 laboratories in this country which are engaged in interstate commerce.

H.R. 14319 as amended, the Clinical Laboratories Improvement Act of 1976, would extend the power of the Federal Government to thousands of intrastate laboratories as well. This bill ignores the fact that over half of the states now regulate clinical laboratories within their jurisdictions. Therefore, this legislation would be illustrative of the fact that too often the Federal Government over-extends its supervision where individual states could better handle the varying problems around this country. Contrary to the findings of the Committee, I am far from convinced that intrastate compliance with laboratory standards made mandatory by this legislation is necessary to prevent depressing interstate commerce or, indeed, that all clinical laboratory testing substantially affects interstate commerce.

The quality of laboratory services is admitted by proponents of this bill to be considerably better than it was a decade ago. Yet, apparently this improvement is overlooked by those who place unlimited trust in the judgment of the Washington bureaucrats of the administrative unit within HEW which would be created to enforce this bill should it be enacted. This bureaucracy would, of course, generate many burdensome administrative requirements and expenses which would further inflate soaring health costs.

It is alleged that the error rate for laboratory tests is too high. Though I regret any inaccuracies, I am not persuaded that the proper remedy for the pursuit of the prefectability of man is action by the Federal Government. Indeed, in light of experience, there is every prospect that the Federal bureaucracy will, through duplicated and burdensome regulations, lead to more confusion.

One of the ill-advised portions of H.R. 14319 is that which provides for employee protection. Actually, employee perpetuation would be a more apt characterization. By that provision no employer may discharge or otherwise penalize any employee because such employee assisted or participated in any action to carry out any of the purposes of the bill. Needless to say, an involved administrative and judicial procedure is set forth to implement this provision.

It is unpersuasively argued that the employee protection portion of the bill is necessary to encourage the pursuit of national goals. The recent unfortunate actions of the Committee on Interstate and foreign Commerce in adopting similar sections in the Clean Air bill this year and the Safe Drinking Water Act in the 93rd Congress are scarcely supportive of the efficacy of such a provision. For, these unwelcome precedents have not yet been digested by experience in the real world.

Rather, it is only a demonstration of an unhappy tendency to liberal doctrine that is not pragmatic. This part of the bill would greatly complicate employer-employee relations by making it more difficult to dislodge incompetent or unsuitable employees because of the spectre of a burdensome discharge process. Perhaps it would be indelicate to dwell at length upon the obvious potential for blackmail by disgruntled employees.

In short, this legislation goes to excessive lengths to correct perceived problems. The American people today want less government. They want less bureaucracy. Americans want lower taxes. We do not need this additional level of legal regulation.

JAMES M. COLLINS.

ADDITIONAL VIEWS OF MESSRS. BROYHILL, BROWN OF OHIO, AND McCOLLISTER ON H.R. 14319

Section 4 of H.R. 14319, as amended, the Clinical Laboratory Improvement Act of 1976, contains several amendments to the Social Security Act.

It may be that many, if not all, of those amendments are efficacious, for few programs are more in need of constructive reform than those administered under the Social Security Act. However, the Subcommittee on Health and the Environment has not held hearings on all of these particular amendments. Thus, while the abuse and fraud related to the Social Security Act has been shockingly clear, it is less certain that this specific proposal represents the proper vehicle for correcting the problem.

One of the provisions in section 4 would add a new section 1132 to the Social Security Act to prohibit reimbursement for any element of a cost or charge for clinical laboratory services (other than services which are provided by a clinical laboratory which is located in a hospital and which provides services primarily in connection with the furnishing by the hospital of other inpatient or outpatient services) which is (1) either a commission or finders fee, or (2) an amount payable for rental or lease of a facility which amount is unrelated or disproportionate to the fair market value of the facility or which is determined as a percent, fraction, or portion of the cost of the laboratory services involved.

The intent of section 1132 is to eliminate kickback arrangements under which some physicians have referred patients to certain independent laboratories that, in turn, have returned a portion of their charges to a physician. Nevertheless, whereas this section is an attempt to curb fraud, it also significantly alters reimbursement arrangements and contracts.

We are, of course, cognizant of the fact that an enlightening report on fraud and abuse among clinical laboratories was prepared by the Subcommittee on Long-Term care of the Senate Special Committee on Aging. Indeed, that Subcommittee recently has held dramatic hearings on the lack of controls in Medicaid. Further, a provision identical to section 1132 is contained in Senator Herman Talmadge's bill, S. 3205, the Medicare-Medicaid Administration and Reimbursement Reform Act. In late July, hearings were held on that bill by the Senate Finance Committee's Subcommittee on Health. However, the printed record is not yet completed and available for analysis.

Because section 1132 has such a major impact on contractual arrangements, we feel that it should have been the subject of hearings by our Subcommittee on Health and the Environment in order to give affected parties an opportunity to testify on the precise language contained in our bill. Thereafter, language could have been developed in full knowledge of all ramifications thereof.

Section 4 would also amend section 1902(a)(23) of the Social Security Act to give States the option under their Medicaid program to seek competitive bids for the purchase of laboratory services. It may be that this will prove to be an attractive cost-saving mechanism. On the other hand, this also could have the unfortunate consequence of allowing the big laboratories to utilize their superior financial positions to outbid smaller concerns. If that were so, numerous smaller laboratories could be forced out of business to the detriment of both variety for the American public and, indeed, competition in the marketplace.

Also, a portion of section 3 of this bill bothers us in that it would amend section 353(k) of the Public Health Service Act to allegedly provide for employee protection. Whereas we realize that our Committee has recently reported other bills containing such language, we are convinced that such previous actions, though precedents, do not establish the desirability of such a provision.

The employee protection provision could potentially undercut one of the central purposes of this bill, namely the asssurance that only qualified, competent personnel are performing testing procedures. This result could occur where the laboratory owner or operator believes that a particular employee, while superficially meeting the personnel qualifications, is not performing adequately. Should the owner or operator seek to terminate the employee's employment or change the terms and conditions of such employee's employment, this provision could allow the employee to attempt to insulate himself from such action by notifying the relevant laboratory licensing agency that the laboratory is not in compliance with the laboratory requirements pursuant to this Act.

If the employee filed such notification, even if it were not meritorious, the owner or operator would have two choices. On the one hand, he could, in order not to jeopardize the laboratory's license, proceed with his proposed action against the employee and possibly subject himself to a complaint to the Secretary of Labor by the employee. On the other hand, the owner or operator, in order to avoid a complaint to the Secretary of Labor, could refrain from his proposed action against the unsatisfactory employee thus jeopardizing the laboratory's ability to meet the federal or state laboratory standards.

Thus, in this situation, the lab is in a "Catch 22" position. Surely, the Congress does not wish to tie the hands of the laboratory owner or operator who wishes to achieve excellence in his laboratory. We fear that this provision, if retained, could do just that.

JAMES T. BROYHILL.
CLARENCE J. BROWN.
JOHN Y. MCCOLLISTER.

SECTION-BY-SECTION ANALYSIS

Section 1 of the bill consists of the bill's short title. It provides that the bill may be cited as the "Clinical Laboratory Improvement Act of 1976".

Section 2 of the bill consists of Congressional findings.

Section 3 of the bill consists of amendments to Section 353 of the Public Health Service Act, (hereinafter, the "Act") entitled "Regulation and Licensing of Clinical Laboratories".

New section 353 (a) of the Act consists of definitions of the terms "laboratory" and "clinical laboratory" and the term "interstate commerce". The definition of "laboratory" and "clinical laboratory" differs from existing law in that collection stations are included within such definition.

New section 353 (b) of the Act establishes requirements applicable to the Secretary of Health, Education, and Welfare (hereinafter referred to as "the Secretary", except that references to "the Secretary" in the description of new section 353 (k) of the Act refer to the Secretary of Labor) with respect to national standards for and proficiency examinations of clinical laboratories.

This subsection requires that within 180 days after the date of enactment of the bill, the Secretary shall publish proposed national standards for clinical laboratories. Further, it requires that such standards be promulgated within one year after the date of enactment (with such modifications as may be appropriate). It also provides that such standards may be amended from time to time.

This subsection requires that national standards be designed to assure consistent performance by clinical laboratories of accurate tests and other procedures and services and that such standards shall:

(1) require laboratories to maintain quality control programs;

(2) require laboratories to maintain records, equipment, and facilities as may be necessary;

(3) include requirements for periodic proficiency testing of laboratories;

(4) prescribe qualifications (which may include licensure, training, and experience requirements or any combination of such requirements) for directors of laboratories;

(5) prescribe qualifications for supervisory personnel of laboratories, which shall require that such personnel (a) meet experience requirements and (b) meet training requirements or successfully complete applicable proficiency examinations;

(6) prescribe qualifications for technologists employed in laboratories, which shall require that technologists (a) meet experience requirements, (b) meet training requirements, or (c) complete applicable proficiency examinations;

(7) prescribe qualifications for technicians employed in laboratories, which shall require the laboratory employing technicians to provide assurances satisfactory to the Secretary that (a) the technician will be employed under the supervision of a qualified director, supervisor or technologist, (b) the technician will be required to complete, at least annually, practical examinations, to be administered by the director of the laboratory, and (c) the technician will perform only those duties which he is qualified to perform, as determined by such practical examinations; and

(8) contain provisions for the enforcement of standards, including provisions for inspection and quality control.

Subsection (b) requires that qualifications with respect to supervisory personnel and technologists shall include each of the alternatives specified above.

Further, this subsection provides definitions of the terms "technologist" and "technician". The term "technologist" is defined as an individual employed in a laboratory who in performing tests or pro-

cedures is required to exercise independent judgement; the term "technician" is defined as a person employed in a laboratory who is not required to exercise independent judgement.

This subsection authorizes national standards for clinical laboratories to vary on the basis of the type of tests, procedures, or services performed by laboratories or the purposes for which such tests, procedures, or services are performed.

Further, the subsection requires that the Secretary shall administer and enforce national standards for clinical laboratories.

Finally, subsection (b) requires that, within one year of the date of enactment of the bill, the Secretary, in consultation with appropriate professional organizations, shall (1) develop job related proficiency examinations for supervisory personnel and technologists in laboratories and (2) promulgate regulations prescribing practical examinations for technicians, both of which shall be utilized in connection with national standards.

New section 353 (c) of the Act governs the application of national standards promulgated pursuant to the bill. It provides that national standards shall (except, as noted below in the description of this subsection and section 353 (h)) apply to each clinical laboratory engaged in interstate commerce and (2) apply to any other clinical laboratory locaetd in a State which does not have primary enforcement responsibility (described below).

This subsection requires the Secretary, upon request of a State which has primary enforcement responsibility, to authorize the State to regulate, pursuant to its standards, interstate clinical laboratories located or doing business within the State. Further, it provides that national standards do not become applicable to clinical laboratories not engaged in interstate commerce until two years following the date that such standards take effect. In addition, it provides that during the two year period beginning on the date that national standards are first made applicable to laboratories (which date would be, in the case of interstate laboratories, the date on which standards take effect and, in the case of intrastate laboratories, two years after such date) the provisions of standards prescribing qualifications for supervisory personnel or for technologists (or both) shall not apply to a laboratory which (1) the Secretary determines is located in a rural area in which individuals with such qualifications are not available, (2) performs services solely for hospitals and health personnel located within the rural area, and (3) provides assurances that it will take such actions as may be necessary to train individuals to meet such qualifications or to employ individuals with such qualifications.

Further, this subsection provides for exemptions from compliance with national standards in four instances;

First, national standards shall not apply to clinical laboratories which are located in the office of, and operated by, a licensed physician, dentist, or podiatrist (or a group of such practitioners) and in which the only tests or procedures which are performed in the laboratory are tests or procedures performed by such practitioners in connection with the treatment of their own patients.

Second, the legislation requires the Secretary, upon application, to exempt from national standards any clinical laboratory (1) which is located in the office of, and operated by, a licensed physician, dentist

or podiatrist or a group of not more than five such practitioners, (2) in which the only tests or procedures performed in the laboratory are tests or procedures performed solely in conjunction with the treatment of the patient of such practioners, and (3) in which the only tests or procedures performed in the laboratory are performed by the practitioners who own or operate the laboratory and routine tests, or only such routine tests or procedures. The application for exemption is required to include information concerning the number and type of tests and procedures conducted in the laboratory, qualifications of personnel who participate in the conduct of tests or procedures or the collection and transmission of specimens, the quantity and type of tests and procedures conducted by such personnel, the type of proficiency testing (if any) participated in by such personnel, and the scores received in such testing, and a description of the quality control programs in effect in such laboratories.

Third, the Secretary is required, upon application, to exempt from national standards any clinical laboratory in which the only tests or procedures which are performed are tests or procedures for research (other than research to determine the course of treatment for a patient).

Fourth, national standards shall not apply to clinical laboratories in which the only tests or procedures performed are tests or procedures for persons engaged in the business of insurance for the purpose of determining whether to write an insurance contract or determine eligibility for payments under an insurance contract.

Further, this subsection prohibits, a State or political subdivision from adopting or continuing in effect requirements (other than personnel licensing requirements) which are applicable to clinical laboratories and different from national standards unless the State has primary enforcement responsibility (described below).

Finally, subsection (c) provides that any clinical laboratory which is engaged in business in interstate commerce shall, during the period beginning on the date of enactment of the bill and ending on the date on which the laboratory is required to have in effect a license issued under the provisions of the bill, comply with licensing requirements in effect under section 353 of the Public Health Service Act prior to its being amended by the bill.

New section 353 (d) of the Act governs the assumption by States of primary enforcement responsibility for the purpose of regulating the quality of the clinical laboratories.

This subsection provides that a State has primary enforcement responsibility when the Secretary determines that the state (1) has adopted (a) standards applicable to clinical laboratories which are no less stringent than national standards and (b) a system for the licensure of laboratories which meets the requirements set forth below with respect to primary enforcement responsibility as well as conditions respecting the issuance or renewal of a license of a laboratory subject to national standards, and provisions respecting the suspension and revocation of and eligibility for licenses which are no less stringent than provisions set forth in the bill with respect to laboratories subject to national standards, (2) has adopted and is implementing adequate procedures for the enforcement of standards, (3) will keep such records and reports with respect to licensing and enforcement as the

Secretary may require, (4) if it permits exemptions from requirements, permits exemptions under conditions and in a manner no less stringent than those applicable in instances in which a laboratory is subject to national standards, (5) has adopted and can implement adequate procedures for control of health hazards resulting from clinical laboratories, and (6) has designated a single agency to enforce its standards and administer its licensure system.

Further, this subsection provides that, for the purpose of primary enforcement responsibility, a State system for the licensure of clinical laboratories (1) shall prescribe that licenses shall be valid for a period not in excess of 24 months and may require a fee for the issuance or renewal of a license in an amount not in excess of $500, (2) may provide for variances in such fees based upon volume of tests or procedures, and (3) must provide that licenses issued for clinical laboratories shall specify the categories of tests and procedures which the laboratory is authorized to perform.

This subsection provides that clinical laboratories subject to regulation by a State which has primary enforcement responsibilities are all clinical laboratories located within the State which are not engaged in business in interstate commerce other than certain Federal clinical laboratories which are exempt pursuant to the provisions of subsection (h) (described below), and, if authorized under the provisions of subsection (c), interstate laboratories located or doing business within the State (except laboratories exempt under subsection (h)).

This subsection further provides that the Secretary shall, within one year of the date of enactment of the bill, propose regulations which prescribe the manner in which a State may apply to the Secretary for determination that the requirements relating to primary enforcement responsibility are satisfied, the manner in which the determination shall be made, the period for which the determination shall be effective, and the manner in which the Secretary may determine that such requirements are no longer met. It requires the Secretary, at least every two years, to review the clinical laboratory regulatory activities of a State with primary enforcement responsibility to determine if the State continues to meet such requirements. It provides that such regulations require that, before any determination of the Secretary that a State does not have or no longer has primary enforcement responsibility becomes effective, the Secretary must notify the State of the determination and the reasons therefor, provides an opportunity for a public hearing on such determination, and, in the case of a determination that the requirements are no longer being met by a State, prescribe the period in which the State must comply with the requirements in order to retain its primary enforcement responsibility. Regulations with respect to primary enforcement responsibility must be promulgated within 90 days of their publication in the Federal Register. Following their promulgation, the Secretary is required to promptly notify in writing the chief executive officer of each State. The notification must contain a copy of the regulations as well as specify a State's authority when it is determined to have primary enforcement responsibility. Finally, this subsection requires that within 90 days of the date on which an application for a determination as to whether a State has primary enforcement responsibility has been submitted, the Secretary is required to make such determination

or deny the application and notify the applicant in writing of the reasons for the denial.

New section 353(e) of the Act requires the Secretary to establish a system for the licensure of clinical laboratories subject to national standards. It provides that a license is to specify the categories of tests and procedures which a laboratory may perform and is to be valid for such period as the Secretary may prescribe, but not in excess of 24 months. It authorizes the Secretary to require a fee for the issuance or renewal of a license but in an amount not to exceed $500. Such fees may vary based upon the volume of tests or procedures performed by clinical laboratories.

Further, this subsection requires that the system for licensure of clinical laboratories established by the Secretary must include the following conditions to the issuance or renewal of the license: (1) submission of an application, (2) a determination that the applicant meets national standards, and (3) submission by the applicant to the Secretary and to the health systems agencies serving the area in which the applicant is located of a schedule of fees the applicant charges for laboratory services and such information as may be necessary to disclose any contractual relationships in effect between the applicant and physicians and other health professionals respecting the laboratory's services and the terms of any contracts between the applicant and such person. It provides that a health system agency may not disclose the identity of any person for whom an applicant for a license performed services except in response to a request of an officer or employee of the United States or of a State in conjunction with the enforcement of section 353 of the Public Health Service Act or of Federal or State criminal law. Further, a health system agency is not authorized to disclose any contractual relationships except (1) contractual relationships between the applicant and any physician for the performance of services if the applicant receives compensation under titles XVIII or XIX of the Social Security Act and (2) contractual relationships in response to a request of an officer or employee of the United States or state in connection with enforcement of section 353 of the Public Health Service Act or a Federal or state criminal law.

Finally, this subsection contains provisions with respect to the suspension and revocation of licenses, and eligibility to apply for a license.

First, it provides that if the Secretary finds, after notice and opportunity for hearing, that (1) a laboratory is not in compliance with national standards or (2) the owner or operator of the laboratory has failed to comply with reasonable requests of the Secretary for information or material necessary to determine the laboratory's continued eligibility for its license or continued compliance with national standards or (3) the owner or operator has refused a request of the Secretary or other Federal officer or employee designated by the Secretary for permission to inspect the laboratory and its operations and pertinent records at any reasonable time, the Secretary may suspend the laboratory's license until the owner or operator demonstrates that the laboratory is in compliance with national standards or that he will comply with any such request, as the case may be.

Second, this subsection provides that if the Secretary finds, after reasonable notice and opportunity for hearing, that the owner or oper-

ator of a clinical laboratory (1) has been guilty of misrepresentation in obtaining a license, (2) has engaged or attempted to engage in, or represented himself as entitled to perform, laboratory tests or procedures not authorized by the license, or (3) has engaged in a billing practice under which charges for laboratory services for a patient whose behalf reimbursement for such charges is provided under a program receiving Federal financial assistance are made at a higher rate than charges for such services provided a patient for whom such reimbursement is not made, the Secretary may revoke the license for the remainder of its term or make the owner or operator ineligible to apply for a license for a period not to exceed 2 years, or take both such actions. Differences in administrative costs related to receiving reimbursement for the provision of services are not to be considered in determining whether the owner or operator has engaged in a discriminatory billing practice.

Third, this subsection requires that any person who is convicted under the provisions of section 353(j) of the Public Health Service Act as added by this bill (relating to operating a clinical laboratory without a proper license and engaging in fraudulent billing practices) or convicted under section 1877(b) or 1909(b) of the Social Security Act (the "anti-fraud" provisions of the Medicare and Medicaid laws) shall not be eligible to apply for a license for a clinical laboratory during the ten-year period beginning on the date that such person's conviction became final and further requires that the license for the laboratory involved in the violation shall be revoked.

New section 353(f) of the Act relates to judicial review of final action taken with respect to revocation or suspension of, or ineligibility to apply for, a license. It authorizes a person aggrieved by such action to file a petition for judicial review of the action in the United States Court of Appeals for the circuit where the person resides or has his principal place of business at any time within 60 days after the date of the action. It requires that a copy of such petition be transmitted by the clerk of the court to the Secretary or to the officer designated by the Secretary for such purpose. Upon receipt of the petition, the Secretary is required to file in the court the record upon which his action was based, as provided in section 2112 of title 28, United States Code (relating to the filing and contents of Federal agency records to be reviewed in courts of appeals). It provides that if the petitioner applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that such evidence is material and that there were reasonable grounds for failure to adduce the evidence in the proceeding before the Secretary, the court may order such additional evidence, as well as evidence in rebuttal of the additional evidence, to be taken before the Secretary and to be adduced upon the hearing. The Secretary is authorized to modify his findings as to the facts or make new findings by reason of such additional evidence and file such modified or new findings and any recommendations for the modification or setting aside of his original action with the return of the additional evidence. Further, this subsection requires that upon the filing of the petition for review, the court of appeals shall have jurisdiction to affirm the action or to set it aside in whole or in part, temporarily or permanently. It requires that the findings of the Secretary as to the facts, if supported by substantial evidence,

shall be conclusive. Finally, this subsection requires that the judgment of the court of appeals shall be final, subject to review by the United States Supreme Court upon certiorari or certification as provided in section 1254 of title 28, United States Code (relating to methods of review by the Supreme Court of cases in the courts of appeals).

New section 353(g) of the Act relates to agreements with entities to assist the Secretary and States in the enforcement of national standards. It authorizes the Secretary and any State with primary enforcement responsibility to enter into agreements with qualified public or non-profit private entities which have adopted standards at least as stringent as national standards or applicable State standards under which agreements such entities would (1) make such inspections as the Secretary or State may require to assure compliance with applicable standards or (2) administer such proficiency tests and periodic examinations as the Secretary or State may require for laboratories and their personnel, or (3) do both.

New section 353(h) of the Act governs the applicability of national standards to Federal clinical laboratories. It provides that clinical laboratories under the jurisdiction of the Secretary and any other Federal clinical laboratory shall be subject to national standards unless (1) the laboratory is under the jurisdiction of the Armed Forces of the United States or the Administrator of Veterans' Affairs, or (2) the agency which has jurisdiction over the laboratory has in effect standards for the laboratory which are no less stringent than national standards. It provides that the Secretary shall bring national standards to the attention of the Secretary of each military department and the Administrator of Veterans' Affairs so that such standards may be considered and applied as appropriate by such persons to laboratories under their jurisdiction.

New section 353(i) of the Act provides authority to the Secretary in connection with enjoining activities of clinical laboratories. It authorizes the Secretary, when he has reason to believe that continuation of any activity by a clinical laboratory required to be licensed by him would constitute a significant hazard to the public health, to bring suit in the United States district court of the district in which the laboratory is situated to enjoin continuation of the activity and requires the court, upon proper showing, to issue a temporary injunction or temporary restraining order against continuation of such activity pending issuance of a final order.

New section 353(j) of the Act prescribes prohibited acts with respect to clinical laboratories and penalties for performing such acts. This subsection provides that any person who solicits or accepts, directly or indirectly, any specimen for a laboratory test or other procedure by a laboratory which is required to be licensed by the Secretary and which does not have such a license in effect or which is not authorized by its license to perform such test or procedure, shall be fined not more than $10,000 or imprisoned for not more than one year, or both. Further, this subsection provides that any owner, operator, or employee of a clinical laboratory who willfully engages in any false, fictitious, or fradulent billing practice for the purpose of obtaining payment for laboratory services under titles V, XVIII, XIX of the Social Security Act shall be fined not more than $10,000 or imprisoned for not more than three years, or both.

Further, this subsection prohibits clinical laboratories required to have in effect a license issued by the Secretary or by a State with primary enforcement responsibility which do not have such a license from receiving a grant, contract or other form of financial assistance under the Public Health Service Act or charge or collect for laboratory services for an entity which received a grant, contract or other form of assistance under the Public Health Service Act. In addition, the charges of such a laboratory may not be included in determining Federal payments under title XVIII of XIX of the Social Security Act.

New section 353(k) of the Act relates to protection of employees of clinical laboratories. This subsection provides that no employer may discharge or otherwise discriminate against any employee with respect to compensation or the terms, conditions or privileges of employment because the employee or a person acting pursuant to the request of the employee has (1) commenced or caused to be commenced a proceeding under section 353 of the Public Health Service Act or a proceeding by a state in carrying out its primary enforcement responsibility; (2) testified, or is about to testify, in any such porceeding; or (3) assisted or participated, or is about to assist or participate, in such proceeding or in any other action to carry out the purpose of section 353.

Further, the subsection provides that any employee who believes that he has been discharged or otherwise discriminated against by a person in violation of the provisions outlined above may, within 30 days after the alleged violation occurs, file a complaint with the Secretary of Labor (hereinafter, in the description of this subsection only, referred to as the "Secretary") alleging such discharge or discrimination and further provides that, upon receipt of such complaint, the Secretary shall notify the person named in the complaint of its filing. Upon receipt of such a complaint, the Secretary is required to conduct an investigation of the violations alleged and, within 30 days of receipt of the complaint complete the investigation and notify the complainant in writing, as well as the person alleged to have committed the violation, of the results of the investigation. Within 90 days of receipt of the complaint, unless the proceeding has been terminated by the Secretary because of a settlement entered into by the Secretary and the person alleged to have committed the violation, the Secretary is required to issue an order which either provides relief or denies the complaint. A settlement terminating a proceeding may not be entered into by the Secretary without the participation and consent of the complainant. If the Secretary determines that a violation of this subsection has occurred, he must: (1) require the person who committed the violation to take affirmative action to abate the violation, (2) require such person to reinstate the complainant to his former position together with the compensation and terms, conditions and privileges of the complainant's employment (including back pay), (3) order the award of compensatory damages, and (4) where appropriate, order the award of exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the amount of all costs and expenses reasonably incurred by the complainant for or in connection with the bringing of the complaint.

The subsection provides for judicial review of any order described above. Judicial review is to be obtained in the United States court of appeals for the circuit in which the violation allegedly occurred. The petition for review must be filed within 60 days from the issuance of the order of the Secretary and review is to be under the conditions of chapter 7 of title 5 of the United States Code (applicable provisions of the Administrative Procedure Act). Any order of the Secretary with respect to which review may be obtained under these provisions shall not be subject to judicial review in any criminal or other civil proceeding.

Further, this subsection provides that whenever a person has failed to comply with an order issued by the Secretary of Labor, the Secretary shall file a civil action in United States district court for the district in which the violation was found to occur in order to enforce the order. In such actions, the district courts shall have jurisdiction to grant appropriate relief including injunctive relief and compensatory and exemplary damages. Such actions must be heard and decided expeditiously. Further, this subsection provides that any non-discretionary duty imposed by this subsection is enforceable in mandamus proceedings brought under section 1361 of title 28, United States Code (relating to actions to compel officers of the United States to perform their duties).

Finally, this subsection provides that its terms are not applicable with respect to any employee who, acting without direction from his employer (or any agent of the employer) deliberately causes a violation of any requirement of section 353 of the Public Health Service Act or of a State wtih primary enforcement responsibility.

New section 353(l) of the Act provides inspection authority with respect to clinical laboratories. It authorizes officers, employees or agents designated by the Secretary to enter and inspect, at reasonable times and in a reasonable manner, any clinical laboratory subject to national standards. Such inspection may extend only to pertinent equipment, materials, containers, records, files, papers (including financial data, sales data and pricing data) processes, controls, facilities and all other things in a laboratory bearing upon whether it is being operated in compliance with section 353 of the Public Health Service Act or regulations issued under such section. It requires that before such officer, employee or agent may make an entry and inspection of a clinical laboratory he must give notice and present appropriate credentials to the owner, operator, or agent in charge. Further, upon completion of any inspection and prior to leaving the premises, the officer, employee or agent is required to give to the owner, operator or agent in charge a preliminary report which summarizes any conditions or practices observed which in the judgment of the inspector indicate a violation of national standards. The inspector must also prepare a written final report of his findings and send it to the owner, operator or agent within 30 days of completion of the inspection. Finally, this subsection provides that no officer, employee, or agent designated to enter a laboratory and conduct an inspection shall be required to obtain a search warrant prior to entering the laboratory and conducting any inspection which is authorized by this subsection.

New subsection 353(m) of the Act authorizes grants to States with primary enforcement responsibility. This subsection provides that in

addition to financial assistance provided to States under title VXIII of the Social Security Act for the enforcement of the standards applicable to clinical laboratories, the Secretary may also make grants to States which have achieved primary enforcement responsibility in order to assist them in meeting the cost of administering and enforcing their clinical laboratory regulatory programs. No such grant may exceed 75% of the State's cost of administering and enforcing its program of regulations of clinical laboratories. In addition, no such grant may be made unless an application has been submitted to and approved by the Secretary. The application must be submitted in such form and contain such information as the Secretary may reasonably require. Authorizations of $3.75 million are provided for each of fiscal years, 1979, 1980 and 1981 for the purpose of making such grants.

New subsection 353(n) of the Act requires the establishment of an advisory council with respect to clinical laboratories. This subsection establishes within the Department of Health, Education, and Welfare an advisory council on clinical laboratories which is to advise, consult with, and make recommendations to the Secretary with respect to regulations promulgated under section 353 of the Public Health Service Act, the implementation and administration of section 353, and coordination between Federal and State clinical laboratory regulatory programs for the purpose of avoiding duplicate enforcement. The advisory council is required to be composed of individuals who as a result of their training, experience, or attainments are well qualified to assist in carrying out its functions. Membership is required to include representatives of the following: (1) nationally recognized laboratory accrediting bodies; (2) directors of state laboratory licensing programs; (3) owners, operators, or directors of laboratories; (4) members of professional and other associations concerned with laboratories and laboratory personnel; (5) representatives of laboratories which are subject to section 353 of the Public Health Service Act and which are engaged in research; (6) representatives of hospitals and (7) members of the public. This subsection provides that members of the advisory council to be appointed from the public shall be individuals who are not employed by or do not receive, either directly or through a spouse, any income from clinical laboratories or any entity which is a supplier of clinical laboratories. Further, the Secretary is required to make appointments to the advisory council in such a manner that the membership is fairly representative of the interests of the persons and entities which its membership is required to include. Finally, this subsection provides that section 222(b) of the Public Health Service Act (relating to compensation of members of advisory councils appointed by the Secretary) shall apply with respect to members of the advisory council established pursuant to the subsection.

New section 353(o) of the Act provides for assistance to regional laboratories. It authorizes the Secretary, acting through the Center for Disease Control, to enter into contracts with State public health laboratories to assist them in the conduct of tests to determine the presence and quantity of carcinogenic and other toxic substances in humans and authorizes appropriations of $3 million for fiscal year 1978 for such purpose.

New section 353(p) of the Act governs the administration of section 353 of the Public Health Service Act. This subsection requires

the Secretary to establish within the Department of Health, Education, and Welfare and under the direct supervision of the Assistant Secretary for Health an identifiable administrative unit which shall be responsible for coordination of the regulatory functions authorized by section 353 as well as the laboratory certification and regulatory functions authorized by titles XVIII and XIX of the Social Security Act.

New section 353(g) of the Act establishes requirements with respect to reports to the Congress. This subsection requires that not later than January 1, 1979 and January 1 of each succeeding year the Secretary make a report to the Congress with respect to the accuracy of tests and procedures performed by clinical laboratories during the preceding fiscal year and evaluating the effect of the costs of clinical laboratory tests and procedures on the over all cost of health care services in relationship of the cost of such tests and procedures to the cost of the health care services for which the tests and procedures are conducted.

Section 4 of the bill contains amendments to the Social Security Act with respect to the regulation of clinical laboratories as follows:

(1) It adds a new section 1132 to such Act which establishes procedures for the determination of reasonable costs and reasonable charges attributable to clinical laboratory services. This section requires that, in determining the amount of any payment for a clinical laboratory service under titles V, XVIII, or XIX of the Act (other than services which are provided by a clinical laboratory which is located in a hospital and which provides services primarily in connection with the furnishing of inpatient or outpatient services by the hospital) no reimbursement will be available for any element of the cost or charge for such service to the extent that such element is (1) a commission or finder's fee or (2) an amount payable for any facility or part or activity thereof under any rental or lease arrangement, where such amount (a) is unrelated or disproportionate to the market value of the facility or part thereof or (b) is directly or indirectly determined wholly or in part as a percent, fraction, or portion of the cost or charge attributable to the laboratory service performed by or for the provider of the services.

(2) It amends section 1902(a)(23) of such Act (governing requirements for a State plan for medical assistance under the Medicaid program and exceptions to such requirements) to authorize a State to make arrangements (through a competitive bidding process or otherwise) for the purchase of clinical laboratory services in instances in which the Secretary has found that (a) adequate services will be available under such arrangements (b) such services will be provided only through laboratories which, during the two-year period beginning on the date of enactment of the bill, meet the requirements of section 1861(e)(9) of the Social Security Act (relating to requirements for a hospital) or paragraphs (10) and (11) of section 1861(s) of such Act (relating to requirements for clinical laboratories whose services are eligible for reimbursement under the Medicare program) and, after the expiration of such two-year period, are licensed

in accordance with section 353 of the Public Health Service Act as amended by the bill and (c) charges for services provided under such arrangements are made at the lowest rate charged (exclusive of administrative costs solely related to the method of reimbursement for such services) for comparable services by the provider of such services or, if charged for on a unit price basis, such charges result in aggregate expenditures not in excess of expenditures that would be made if charges were at the lowest rate charged for comparable services by the provider.

(3) It amends section 1902 (a)(28) of such Act (relating to the requirements of the State plan for medical assistance) to require that any laboratory services paid for under such plan be provided by a laboratory which during the two-year period beginning on the date of enactment of this bill meets the requirements of section 1861(e)(9) of the Social Security Act or paragraphs (10) and (11) of section 1861(s) of the Act and after the expiration of such period are licensed in accordance with section 353 of the Public Health Service Act as amended by the bill.

(4) It amends section 1902(a)(30) (relating to requirements that State plans for the provision of medical assistance under the Medicaid program assure that payments are not in excess of reasonable charges) to provide that, under such plans, payments for laboratory services do not exceed the lowest amount charged (determined without regard to administrative costs related solely to the method of reimbursement for services) to any person or entity for such services by the provider of laboratory services and, in the case of laboratory services billed for by a physician or laboratory but performed by another person or entity which is not in the employ of the physician or laboratory, do not exceed the lowest amount charged to any person or entity for the laboratory service plus, at the option of the State and if it is determined under regulations prescribed by the Secretary to be reasonable, a nominal charge for any necessary professional service performed by the physician.

(5) It amends sections 1877(b) and 1909(b) of the Social Security Act (which prescribe penalties for persons convicted of soliciting, offering, or receiving any kickback or bribe in connection with the Medicare and Medicaid programs, respectively) to (a) make such offenses felonies instead of misdemeanors, (b) provide that the maximum sentence available to persons who are convicted of such offenses shall be three years instead of one year and (c) provide that a "bribe" under such sections may be in the form of money or any other thing of value.

(6) It provides that, effective three years after the date of enactment of the bill, section 1861(s) of the Act is amended to require that no diagnostic test performed in any clinical laboratory shall be included within the definition of "medical and other health services" (and thus be eligible for reimbursement under the Medicare program) unless the laboratory meets applicable Federal or State licensing requirements under section 353 of the Public Health Service Act as amended by the bill, to require that (after such three-year period) the Secretary may not make

an arrangement with any State to use State agencies to determine compliance with conditions of participation under the Medicare program with respect to clinical laboratory services unless such State has achieved primary enforcement responsibility.

Section 5 of the bill requires that there be conducted a study of procedures and certification of laboratory personnel. This section requires the Secretary of Health, Education, and Welfare, in cooperation with appropriate public and private entities, to conduct a study of (1) existing voluntary certification standards and state licensure laws for clinical laboratory supervisors, technologists, and technicians and (2) qualifications of entities that certify such personnel as qualified to perform laboratory procedures in clinical laboratories licensed under section 353 of the Public Health Service Act. This study must include (1) an assessment of the need for certification of such personnel pursuant to national standards, (2) development of national standards which the Secretary determines should be used as guidelines for entities which certify such personnel, (3) the determination of the numbers of technical laboratory personnel who would meet standards developed by the Secretary and a projection of the numbers of such personnel in calendar years 1980, 1985 and 1990, (4) an analysis of the effect on costs of laboratory tests and procedures and the quality of such tests and procedures of a requirement that only laboratory personnel which meet such standards meet qualifications necessary for a laboratory to be licensed under section 353 of the Public Health Service Act, and (5) an anaylsis of the various entities who certify laboratory personnel including an analysis of the need for participation in certification procedures by members of the public and the financial interests of such entities in clinical laboratories. The Secretary is required to submit to the Congress the results of this study and recommendations for legislation as the Secretary considers necessary within one year of the date of enactment of the bill.

Section 6 of the bill requires a report with respect to the bill's exemption of physician laboratories. This section requires the Secretary of Health, Education, and Welfare to report to the Congress a summary of information received by him under applications submitted under new section 353(c)(2)(D)(ii) of the Public Health Service Act (relating to applications for exemption of certain office-based clinical laboratories) during the three year period beginning on the date national standards are promulgated and, on the basis of such information, make recommendations (1) as to whether clinical laboratories granted exemptions under such clause should be required, as a condition to their exemption, to have laboratory procedure manuals, participate in laboratory proficiency testing programs, and maintain quality control programs prescribed under such standards and (2) whether section 353(c)(2)(D) should otherwise be revised. Such report is required to be submitted within 3 months of the expiration of the three year period.

Section 7 of the bill requires a study of financial arrangements made by hospitals for clinical laboratory services. This subsection requires the Secretary to conduct a study of financial arrangements entered into by hospitals reimbursed under titles XVIII or XIX of the Social Security Act for the provision of clinical laboratory services by per-

sons who provide such services in hospitals to determine if such arrangements are in the public interest. The study is required to include an examination of (1) arrangements between hospitals and providers of clinical laboratory services under which the fee for the provision of such services is based on a percentage of the gross revenues received by the providers for such services, (2) leasing arrangements for facilities and equipment entered into by hospitals and providers of such services and (3) arrangements by hospitals for salaries and other forms of compensation for the providers of such services. Within 6 months of the date of enactment of the bill, the study must be completed and a report must be made to the Congress setting forth the findings of the study and recommendations of the Secretary for such corrective legislation as the Secretary determines to be necessary.

Changes in Existing Law Made by the Bill, As Reported

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman) :

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * * * *

Part F—Licensing—Biological Products and Clinical Laboratories and Control of Radiation

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Subpart 2—Clinical Laboratories

REGULATION AND LICENSING OF *CLINICAL* LABORATORIES

Sec. 353. (a) *Definitions.*—As used in this section—

(1) the term "laboratory" [or] *and* "clinical laboratory" [means] *mean* (*A*) a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human [body,] *body* for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of [man;] *man, or* (*B*) *a facility for the collection, processing, and transmission of such materials for such purposes, other than a facility exclusively engaged in the collection, processing, or transmission of human whole blood or its components.*

(2) The term "interstate commerce" means trade, traffic, commerce, transportation, transmission, or communication between any State or possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

[(b)(1) No person may solicit or accept in interstate commerce, directly or indirectly, any specimen for laboratory examination or other laboratory procedures, unless there is in effect a license for such laboratory issued by the Secretary under this section applicable to such procedures.

[(2) The Secretary by regulation exempt from the provisions of this section laboratories whose operations are so small or infrequent as not to constitute a significant threat to the public health.

[(c) A license issued by the Secretary under this section may be applicable to all laboratory procedures or only to specified laboratory procedures or categories of laboratory procedures.

[(d)(1) A license shall not be issued in the case of any clinical laboratory unless (A) the application therefor contains or is accompanied by such information as the Secretary finds necessary, and (B) the applicant agrees and the Secretary determines that such laboratory will be operated in accordance with standards found necessary by the Secretary to carry out the purposes of this section. Such standards shall be designed to assure consistent performance by the laboratories of accurate laboratory procedures and services, and shall include, among others, standards to assure—

[(i) maintenance of a quality control program adequate and appropriate for accuracy of the laboratory procedures and services;

[(ii) maintenance of records, equipment, and facilities necessary to proper and effective operation of the laboratory;

[(iii) qualifications of the director of the laboratory and other supervisory professional personnel necessary for adequate and effective professional supervision of the operation of the laboratory (which shall include criteria relating to the extent to which training and experience shall be substituted for education); and

[(iv) participation in a proficiency testing program established by the Secretary.

[(2) A license issued under this section shall be valid for a period of three years, or such shorter period as the Secretary may establish for any clinical laboratory or any class or classes thereof; and may be renewed in such manner as the Secretary may prescribe. The provisions of this section requiring licensing shall not apply to a clinical laboratory in a hospital accredited by the Joint Commission on the Accreditation of Hospitals or by the American Osteopathic Association, or a laboratory which has been inspected and accredited by such commission or association, by the Commission on Inspection and Accreditation of the College of American Pathologists, or by any other national accreditation body approved for the purpose by the Secretary, but only if the standards applied by such commission, association, or other body in determining whether or not to accredit such hospital or laboratory are equal to or more stringent than the provisions of this section and the rules and regulations issued under this section, and only if there is adequate provision for assuring that such standards continue to be

met by such hospital or laboratory; provided that any such laboratory shall be treated as a licensed laboratory for all other purposes of this section.

[(3) The Secretary may require payment of fees for the issuance and renewal of licenses, but the amount of any such fee shall not exceed $125 per annum.

[(e) A laboratory license may be revoked, suspended, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

[(1) has been guilty of misrepresentation in obtaining the license;

[(2) has engaged or attempted to engage or represented himself as entitled to perform any laboratory procedure or category of procedures not authorized in the license;

[(3) has failed to comply with the standards with respect to laboratories and laboratory personnel prescribed by the Secretary pursuant to this section;

[(4) has failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, he deems necessary to determine the laboratory's continued eligibility for its license hereunder or continued compliance with the Secretary's standards hereunder;

[(5) has refused a request of the Secretary or any Federal officer or employee duly designated by him for permission to inspect the laboratory and its operations and pertinent records at any reasonable time; or

[(6) has violated or aided and abetted in the violation of any provisions of this section or of any rule or regulation promulgated thereunder.

[(f) Whenever the Secretary has reason to believe that continuation of any activity by a laboratory licensed under this section would constitute an imminent hazard to the public health, he may bring suit in the district court for the district in which such laboratory is situated to enjoin continuation of such activity and, upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this section shall be granted without bond or by such court.

[(g)(1) Any party aggrieved by any final action taken under subsection (e) of this section may at any time within sixty days after the date of such action file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for judicial review of such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

[(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evi-

dence in rebuttal thereof, to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original action, with the return of such additional evievidence.

[(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

[(4) The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

[(h) Any person who willfully violates any provision of this section or any rule or regulation promulgated thereunder shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine.

[(i) The provisions of this section shall not apply to any clinical laboratory operated by a licensed physician, osteopath, dentist, or podiatrist, or group thereof, who performs or perform laboratory tests or procedures, personally or through his or their employees, solely as an adjunct to the treatment of his or their own patients; nor shall such provisions apply to any laboratory with respect to tests or other procedures made by it for any person engaged in the business of insurance if made solely for purposes of determining whether to write an insurance contract or of determining eligibility or continued eligibility for payments thereunder.

[(j) In carrying out his functions under this section, the Secretary is authorized, pursuant to agreement, to utilize the services or facilities of any Federal or State or local public agency or nonprofit private agency or organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as he may determine.

[(k) Nothing in this section shall be construed as a affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with the provisions of this section or with the rules and regulations issued under this section.

[(l) Where a State has enacted or hereafter enacts laws relating to matters covered by this section, which provide for standards equal to or more stringent than the provisions of this section or than the rules and regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.]

(b) National Standards and Proficiency Examinations.—(1) Within one hundred and eighty days of the date of the enactment of the Clincial Laboratory Improvement Act of 1976 the Secretary shall publish proposed national standards for clinical laboratories. Within one year after such date of enactment, the Secretary shall promulgate

such standards with such modifications as the Secretary deems appropriate and such standards shall take effect upon their promulgation. Standards under this subsection may be amended from time to time.

(2)(A) National standards promulgated under paragraph (1) for clinical laboratories shall be designed to assure consistent performance by the laboratories of accurate laboratory tests and other procedures and services and shall—

(i) require laboratories subject to the standards to maintain appropriate quality control programs,

(ii) require such laboratories to maintain such records, equipment, and facilities as may be necessary for the proper and effective operation of the laboratories,

(iii) include requirements for periodic proficiency testing of such laboratories,

(iv) prescribe qualifications (which may include licensure, training, and experience requirements or any combination of such requirements) for directors of such laboratories,

(v) prescribe qualifications for supervisory personnel of such laboratories, which qualifications shall require such personnel—

(I) to meet specified experience requirements, and

(II) to meet specified training requirements, or successfully complete the applicable proficiency examination developed under paragraph (3),

(vi) prescribe qualifications for technologists employed in such laboratories, which qualifications shall require such technologists to—

(I) meet specified experience requirements,

(II) meet specified training requirements, or

(III) successfully complete the applicable proficiency examination developed under paragraph (3),

(vii) prescribe qualifications for technicians employed in such laboratories, which qualifications shall require the laboratory employing the technician to provide assurances satisfactory to the Secretary that—

(I) the technician will be employed under the supervision of a qualified director, supervisor, or technologist,

(II) the technicians will be required to successfully complete, at least annually, practical examinations (prescribed by the Secretary by regulation) to be administered by the director of the laboratory and related to the technician's duties, and

(III) the technician will perform only those duties for which, as determined by such practical examinations, the technician is qualified to perform, and

(viii) contain adequate provisions for the enforcement of the standards, including provisions for inspections and quality control.

Qualifications prescribed under clauses (v) and (vi) shall include as alternative requirements each of the alternative requirements listed in such clauses.

(B) For purposes of subparagraph (A)—

(i) the term 'technologist' means an individual employed in a laboratory who in performing tests or procedures in such laboratory is required to exercise independent judgment, and

(ii) the term 'technician' means a person employed in a laboratory who is not required to exercise independent judgment in the technician's employment by the laboratory.

(C) Standards prescribed under subparagraph (A) for clinical laboratories may vary on the basis of the type of tests, procedures, or services performed by such laboratories or the purposes for which such tests, procedures, or services are performed.

(D) The Secretary shall, in accordance with subsection (c), administer and enforce the national standards promulgated under paragraph (1).

(3) Within one year of the date of the enactment of the Clinical Laboratory Improvement Act of 1976, the Secretary in consultation with appropriate professional organizations, shall (A) develop job-related proficiency examinations for supervisory personnel and technologists in laboratories, and (B) promulgate regulations prescribing practical examinations for technicians.

(c) APPLICATION OF NATIONAL STANDARDS.—(1) National standards for clinical laboratories in effect under subsection (b) shall, except as provided in paragraph (2) and subsection (h)—

(A) apply to each clinical laboratory which is engaged in business in interstate commerce, and

(B) apply to any other clinical laboratory which is located in a State which (as determined under subsection (d)) does not have primary enforcement responsibility for the regulation of clinical laboratories.

(2)(A) The Secretary upon request of a State which has primary enforcement responsibility for the regulation of clinical laboratories shall authorize such State to regulate under the standards of the State described in subsection (d)(1)(A)(i) clinical laboratories located or doing business within the State, as determined by the State, which are described in subparagraph (A) of paragraph (1).

(B) During the two-year period beginning on the date that national standards first take effect under subsection (b) such standards shall not apply to clinical laboratories which are not engaged in business in interstate commerce.

(C) During the two-year period beginning on the date that national standards for clinical laboratories first take effect under subsection (b) (or, in the case of a clinical laboratory which is not engaged in business in interstate commerce, during the two-year period beginning on the date such standards are first made applicable to such laboratories), the provisions of such standards prescribing qualifications for supervisory personnel or the provisions of such standards prescribing qualifications for technologists, or both provisions, shall not apply to a clinical laboratory which—

(i) the Secretary determines is located in a rural area (as defined by the Secretary) in which individuals with the qualifications prescribed by such provisions are not available,

(ii) performs services solely for hospitals and physicians, dentists, or podiatrists (or any combination of such practitioners) located within such rural area, and

(iii) provides the Secretary satisfactory assurances that it will take such actions as may be necessary to train individuals to meet such qualifications or to employ individuals with such qualifications.

(D) (i) The national standards for clinical laboratories shall not apply to any clinical laboratory—

(I) which is located in the office of, and operated by, a licensed physician, dentist, or podiatrist, or a group of such practitioners, and

(II) in which the only tests or procedures which are performed are tests or procedures performed by such a practitioner in connection with the treatment of his patients.

(ii) The Secretary shall, upon application, exempt from the national standards for clinical laboratories any laboratory—

(I) which is located in the office of, and operated by, a licensed physician, dentist, or podiatrist, or a group of not more than five such practitioners and in which the only tests or procedures which are performed are tests or procedures performed in connection with the treatment of the patients of such practitioner (or practitioners), and

(II) in which the only tests or procedures which are performed are tests or procedures described in clause (i)(II) of this subparagraph and routine tests or procedures, as determined by the Secretary, or only such routine tests or procedures.

An application for the issuance of an exemption under this clause shall include an estimation of the number and a specification of the type of tests and procedures conducted in the laboratory for which the application is submitted, a description of the qualifications (including the educational background, training, and experience) of personnel who are not physicians, dentists, or podiatrists and who participate in the conduct of tests and procedures, the collection of specimens, and the transmission of specimens; a specification of the quantity and type of tests and procedures conducted by such personnel; the type of proficiency testing (if any) participated in by such personnel and the scores received in such testing; and a description of the quality control programs in effect in the facility for which the application is submitted.

(iii) The Secretary shall, upon application, exempt, on such terms and conditions as may be appropriate, from the national standards for clinical laboratories any laboratory in which the only tests or procedures which are performed are tests or procedures for research (other than research to determine the course of treatment for an individual patient).

(iv) The national standards for clinical laboratories shall not apply to any laboratory in which the only tests or procedures performed are tests or procedures for persons engaged in the business of insurance for the purpose of determining whether to write an insurance contract or determining eligibility for payments under an insurance contract.

(3) Except as authorized under subsection (d), no State or political subdivision may adopt or continue in effect requirements (other than licensing requirements applicable to directors, supervisory personnel, technologists, or technicians in clinical laboratories) which—

(A) are applicable to clinical laboratories, and

(B) are different from or in addition to the national standards for clinical laboratories in effect under subsection (b).

(4) Any clinical laboratory which is engaged in business in interstate commerce shall, during the period beginning on the date of the enactment of the Clinical Laboratory Improvement Act of 1976 and ending on the date such laboratory is required to have in effect a license issued under this section as amended by such Act, comply with the licensing requirements in effect under this section before such date of enactment.

(d) PRIMARY ENFORCEMENT RESPONSIBILITY.—(1)(A) For purposes of this section, a State has primary enforcement responsibility for the regulation of clinical laboratories described in paragraph (2) during any period for which the Secretary determines (pursuant to regulations prescribed under paragraph (3)) that such State—

(i) has adopted (I) standards applicable to clinical laboratories which are no less stringent than the national standards promulgated under subsection (b), and (II) a system for the licensure of laboratories which meets the requirements of subparagraph (B) of this paragraph and of paragraph (1)(B) of subsection (e) and provisions respecting the suspension, revocation, and eligibility for licenses which provisions are no less stringent than the provisions of paragraph (2) of subsection (e),

(ii) has adopted and is implementing adequate procedures for the enforcement of such State's standards, including conducting such monitoring and making such inspections as the Secretary may require by regulation,

(iii) will keep such records and make such reports with respect to its activities under clauses (i) and (ii) as the Secretary may require by regulation,

(iv) if it permits exemptions from the requirements of its standards which meet the requirements of clause (i)(I), permits such exemptions under conditions and in a manner which are no less stringent than the conditions and the manner in which exemptions may be granted under subsection (c)(2),

(v) has adopted and can implement adequate procedures for the effective and timely control of health hazards which may result from an activity of a clinical laboratory within the State, and

(vi) has designated a single agency of the State to enforce its standards and to administer its system for licensure of clinical laboratories.

(B) For the purpose of primary enforcement responsibility under this subsection, a State system for the licensure of clinical laboratories—

(i) shall prescribe that licenses issued under such system shall be valid for such period (but not in excess of twenty-four months) as is prescribed under the system, and may require a fee for the issuance or renewal of a license in an amount (not in excess of $500) determined under the system;

(ii) may provide for variances in such fees based on the volume of tests or procedures performed by the clinical laboratories subject to such fees; and

(iii) shall provide that licenses issued for a clinical laboratory

shall specify the categories of tests and procedures which such laboratory may perform.

(2) The clinical laboratories subject to regulation by a State which has primary enforcement responsibility are—

(A) clinical laboratories (other than clinical laboratories described in subsection (h)) which are located within such State and which are not engaged in business in interstate commerce, and

(B) if authorized under subsection (c)(2)(A), any other clinical laboratory (other than a clinical laboratory described in subsection (h)) engaged in business in interstate commerce and located or doing business within the State, as determined by the State.

(3)(A)(i) The Secretary shall, by regulation (proposed within one year of the date of the enactment of the Clinical Laboratory Improvement Act of 1976), prescribe the manner in which a State may apply to the Secretary for a determination that the requirements of paragraph (1) are satisfied with respect to the State, the manner in which the determination is made, the period for which the determination will be effective, and the manner in which the Secretary may determine that such requirements are no longer met. The Secretary shall, at least every two years, review the clinical laboratory regulatory activities of a State with primary enforcement responsibility to determine if the State continues to meet the requirements of paragraph (1).

(ii) Regulations under this subparagraph shall require that before a determination of the Secretary that the requirements of paragraph (1) are not met or are no longer met with respect to a State may become effective, the Secretary shall notify such State of the determination and the reasons therefor, shall provide an opportunity for public hearing on the determination, and, in the case of a determination that such requirements are no longer being met by a State, shall prescribe the period within which such State must comply with such requirements to retain its primary enforcement responsibility. Such regulations shall be promulgated (with such modifications as the Secretary deems appropriate) within ninety days of the publication of the proposed regulations in the Federal Register. The Secretary shall promptly notify in writing the chief executive officer of each State of the promulgation of regulations under this subparagraph. Such notice shall contain a copy of the regulations and shall specify a State's authority under this section when it is determined to have primary enforcement responsibility for clinical laboratories.

(B) When an application is submitted in accordance with the Secretary's regulations under subparagraph (A), the Secretary shall within ninety days of the date on which such application is submitted (i) make the determination applied for, or (ii) deny the application and notify the applicant in writing of the reasons for the denial.

(e) LICENSES.—(1)(A) The Secretary shall establish a system for the licensure of clinical laboratories subject, as determined under subsection (c), to national standards promulgated under subsection (b). A license issued under such system for a clinical laboratory (i) shall specify the categories of tests and procedures which such laboratory may perform, and (ii) shall be valid for such period (but not in excess

of twenty-four months) as the Secretary may prescribe. A fee may be required by the Secretary for the issuance or renewal of a license in an amount not to exceed $500. The Secretary may prescribe variances in such fees based on the volume of tests or procedures performed by the clinical laboratories subject to such fees.

(B) The system established under subparagraph (A) shall require the following as a condition to the issuance or renewal of a license under the system:

(i) The submission of an application in such form and manner as may be prescribed by the Secretary.

(ii) A determination by the Secretary that the applicant meets the national standards promulgated under subsection (b).

(iii) The submission by the applicant to the Secretary and to the health systems agency serving the area in which the applicant is located of (I) a schedule of the fees the applicant charges for the laboratory services it provides, and (II) such information as may be necessary to disclose any contractual relationships in effect between the applicant and physicians and other health professionals respecting the laboratory's services and the terms of any contracts between the applicant and such persons.

(C) From the information submitted in accordance with subparagraph (B)(iii) a health systems agency may not disclose—

(i) the identity of any person for whom an applicant for a license performed services except in response to a request of an officer or employee of the United States or a State made in accordance with regulations of the Secretary and in connection with the functions or duties of the officer or employee in the enforcement of this section or of a Federal or State criminal law; and

(ii) any contractual relationship described in subclause (II) of such subparagraph, except that, in accordance with regulations promulgated by the Secretary, the health systems agency may disclose (I) a contractual relationship between the applicant and any physician for the performance of services if the applicant receives compensation under title XVIII of the Social Security Act or under a State plan for medical assistance approved under title XIX of such Act for the performance of clinical laboratory services, and (II) any contractual relationship described in such subclause (II) in response to a request of an officer or employee of the United States or a State made in connection with the functions or duties of the officer or employee in the enforcement of this section or a Federal or State criminal law.

(2)(A) If the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of a clinical laboratory licensed under this subsection, that—

(i) such laboratory is not in compliance with applicable national standards promulgated pursuant to subsection (b), or

(ii) such owner or operator has (I) failed to comply with reasonable requests of the Secretary for any information or materials, or work on materials, the Secretary deems necessary to determine the laboratory's continued eligibility for its license under this subsection or continued compliance with applicable national standards in effect under subsection (b), or (II) refused a request of the Secretary or any Federal officer or employee duly desig-

nated by him for permission to inspect, under subsection (l), the laboratory and its operations and pertinent records at any reasonable time,

the Secretary may suspend such laboratory's license until the owner or operator of such laboratory has demonstrated to the satisfaction of the Secretary that the laboratory is in compliance with such national standards or such requests will be complied with, as the case may be.

(B) If the Secretary finds, after reasonable notice and opportunity for a hearing to the owner or operator of a clinical laboratory licensed under this subsection, that such owner or operator—

(i) has been guilty of misrepresentation in obtaining the license;

(ii) has engaged or attempted to engage in, or represented himself as entitled to perform, any laboratory test or procedure or category of tests or procedures not authorized by the license; or

(iii) has engaged in a billing practice under which charges for laboratory services provided a patient, on whose behalf reimbursement (in whole or in part) for such charges is provided under a program receiving Federal financial assistance, are made at a higher rate than charges for such services provided a patient for whom such reimbursement is not made,

the Secretary may revoke such license for the remainder of its term or may make such persons ineligible to apply for a license under this subsection for such period (not to exceed two years) as the Secretary may prescribe, or take both such actions. A billing practice which results in different charges for the same laboratory services solely because of differences in administrative costs related to receiving reimbursement for the provision of such services shall not be considered a billing practice described in clause (iii).

(C) Any person who is convicted under paragraph (1) or (2) of subsection (j) of this section or under section 1877(b) or 1909(b) of the Social Security Act after the date of enactment of the Clinical Laboratory Improvement Act of 1976 for a violation occurring after such date shall not be eligible to apply for a license under this subsection for a clinical laboratory during the ten-year period beginning on the date such person's conviction became final and the license of the laboratory involved in such violation shall be revoked.

(f) JUDICIAL REVIEW.—(1) Any person aggrieved by any final action taken under subsection (e)(2) of this section may at any time within sixty days after the date of such action file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business for judicial review of such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence

in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

(g) AGREEMENTS.—The Secretary and any State which has primary enforcement responsibility for the regulation of clinical laboratories may enter into agreements with qualified public or nonprofit private entities which have adopted standards at least as stringent as those in effect under this section (or in the case of agreements to be entered into by such a State, at least as stringent as those in effect in such State under subsection (d)) under which agreements such entities would—

(1) make such inspections as the Secretary or such State may require to assure clinical laboratories are in compliance with applicable standards,

(2) administer such proficiency tests and periodic examinations as the Secretary or such State may require for clinical laboratories and the personnel of such laboratories, or

(3) do both.

(h) FEDERAL CLINICAL LABORATORIES.—(1) Federal clinical laboratories under the jurisdiction of the Secretary shall be subject to national standards in effect under subsection (b) and any other Federal clinical laboratory in a State shall be subject to such standards unless (A) the laboratory is under the jurisdiction of any of the Armed Forces of the United States or the Administrator of Veterans' Affairs, or (B) the agency which has jurisdiction over such laboratory has in effect standards for such laboratory which are no less stringent than the national standards in effect under subsection (b).

(2) The Secretary shall bring the national standards promulgated under subsection (b) to the attention of the Secretary of each military department and the Administrator of Veterans' Affairs so that such standards may be considered and applied as appropriate by such Secretaries and Administrator to clinical laboratories under their jurisdiction.

(i) INJUNCTION.—Whenever the Secretary has reason to believe that continuation of any activity by a clinical laboratory required to be licensed under this section by the Secretary would constitute a significant hazard to the public health, he may bring suit in the United States district court for the district in which such laboratory is situated to enjoin continuation of such activity and, upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order by the court shall be granted without bond.

(j) PROHIBITED ACTS.—(1) Any person who solicits or accepts, directly or indirectly, any specimen for a laboratory test or other laboratory procedure by a laboratory which is required to have in effect a license issued by the Secretary under this section and which does not have such a license in effect or which is not authorized by its license to perform such test or procedure, shall be fined not more than $10,000 or imprisoned for not more than one year, or both.

(2) Any owner or operator of a clinical laboratory, or any employee thereof, who willfully engages in any false, fictitious, or fraudulent billing practice for the purpose of obtaining payment for laboratory services provided under title XVIII of the Social Security Act, a program established pursuant to title V of such Act, or a State plan approved under title XIX of such Act shall be fined not more than $10,000 or imprisoned for not more than three years, or both.

(3) No clinical laboratory which is required to have in effect a license issued by the Secretary under this section or a license issued by a State with primary enforcement responsibility for the regulation of clinical laboratories and which does not have such a license in effect may—

(A) receive a grant, contract, or other form of financial assistance under this Act, or

(B) charge or collect for laboratory services for any entity which receives a grant, contract, or other form of financial assistance under this Act.

The charges of such a laboratory may not be included in determining Federal payments under title XVIII or XIX of the Social Security Act.

(k) EMPLOYEE PROTECTION.—(1) No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation or the terms, conditions, or privileges of his employment because the employee (or any person acting pursuant to a request of the employee) has—

(A) commenced or caused to be commenced a proceeding under this section or a proceeding by a State in carrying out its primary enforcement responsibility;

(B) testified or is about to testify in any such proceeding; or

(C) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this section.

(2)(A) Any employee who believes that the employee has been discharged or otherwise discriminated against by any person in violation of paragraph (1) may, within thirty days after such alleged violation occurs, file (or have any person file on the employee's behalf) a complaint with the Secretary of Labor (hereinafter in this subsection referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(B)(i) Upon receipt of a complaint filed under subparagraph (A), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within thirty days of the receipt of such complaint,

the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting on behalf of the complainant) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this subparagraph. Within ninety days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by clause (ii) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(ii) If in response to a complaint filed under subparagraph (A) the Secretary determines that a violation of paragraph (1) has occurred, the Secretary shall order (I) the person who committed such violation to take affirmative action to abate the violation, (II) such person to reinstate the complainant to the complainant's former position together with the compensation (including back pay), terms, conditions, and privileges of the complainant's employment, (III) the award of compensatory damages, and (IV) where appropriate, the award of exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorney's fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(3) (A) Any person adversely affected or aggrieved by an order issued under paragraph (2) may obtain review of the order in the United States court of appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5 of the United States Code.

(B) An order of the Secretary, with respect to which review could have been obtained under subparagraph (A), shall not be subject to judicial review in any criminal or other civil proceeding.

(4) (A) Whenever a person has failed to comply with an order issued under paragraph (2) (B), the Secretary shall file a civil action in the United States district court for the district in which the violation was found to occur to enforce such order. In actions brought under this paragraph, the district courts of the United States shall have jurisdiction to grant all appropriate relief, including injunctive relief and compensatory and exemplary damages. Civil actions brought under this paragraph shall be heard and decided expeditiously.

(B) Any nondiscretionary duty imposed by this subsection is enforceable in mandamus proceeding brought under section 1361 of title 28, United States Code.

(5) Paragraph (1) shall not apply with respect to any employee who, acting without direction from the employee's employer (or any

agent of the employer), deliberately causes a violation of any requirement of this section or of a clinical laboratory regulatory requirement of a State with primary enforcement responsibility.

(l) INSPECTION AUTHORITY.—(1) For purposes of enforcement of this section, officers, employees, or agents designated by the Secretary are authorized to enter and inspect, at reasonable times and in a reasonable manner, any clinical laboratory in a State which is subject to national standards established under subsection (b). Such an inspection may extend only to pertinent equipment, materials, containers, records, files, papers (including financial data, sales data, and pricing data), processes, controls, facilities, and all other things in the clinical laboratory bearing on whether it is being operated in compliance with this section and the regulations issued hereunder. Before such an officer, employee, or agent may make such an entry and inspection of a clinical laboratory he shall give notice, and present appropriate credentials, to the owner, operator, or agent in charge of the laboratory.

(2) Upon completion of any such inspection and prior to leaving the premises, the officer, employee, or agent making the inspection shall give to the owner, operator, or agent in charge a preliminary report which summarizes any conditions or practices observed by him which, in his judgment, indicate a violation of national standards in effect under subsection (b). He shall also prepare a written final report of his findings and send it to such owner, operator, or agent within thirty days of the completion of the inspection.

(3) No officer, employee, or agent designated by the Secretary to enter a laboratory and conduct an inspection pursuant to this subsection shall be required to obtain a search warrant from any judicial officer prior to entering any laboratory and conducting any inspection which is authorized by this subsection.

(m) GRANTS.—(1) In addition to the financial assistance provided to States under title XVIII of the Social Security Act for the enforcement of standards applicable to clinical laboratories under such title, the Secretary may also make grants to States with primary enforcement responsibility to assist them in meeting the cost of administering and enforcing their programs for the regulation of clinical laboratories.

(2) The amount of any grant made under this subsection shall be determined by the Secretary, but no such grant to any State may exceed 75 per centum of such State's cost of administering and enforcing its program of regulation of clinical laboratories.

(3) No grant may be made under this subsection unless an application therefor has been submitted to and approved by the Secretary. Such application shall be submitted in such form and contain such information as the Secretary may reasonably require.

(4) For the purposes of making payments under grants under this subsection there are authorized to be appropriated $3,750,000 for the fiscal year ending September 30, 1979, $3,750,000 for the fiscal year ending September 30, 1980, and $3,750,000 for the fiscal year ending September 30, 1981.

(n) ADVISORY COUNCIL.—There is established in the Department of Health, Education, and Welfare an advisory council on clinical laboratories which shall advise, consult with, and make recommendations to, the Secretary with respect to—

(1) regulations promulgated under this section,

(2) the implementation and administration of this section, and

(3) coordination between the Federal and State clinical laboratory regulatory programs for the purpose of avoiding duplicate enforcement.

The advisory council shall be composed of individuals who, as a result of their training, experience, or attainments, are well qualified to assist in carrying out the functions of the advisory council. The membership shall include representatives of nationally recognized laboratory accrediting bodies; directors of State laboratory licensing programs; owners, operators, or directors of laboratories; members of professional and other associations concerned with laboratories and laboratory personnel; representatives of laboratories which are engaged in research; representatives of hospitals; and members of the public. The Secretary shall make appointments to the advisory council in such a manner that the membership is fairly representative of the interests described in the preceding sentence. Members of the advisory council to be appointed from the public shall be individuals who are not employed by, or do not receive (either directly, or through a spouse) any income from, clinical laboratories or any entity which is a supplier of clinical laboratories. Section 222(b) shall apply with respect to members of the advisory council.

(o) REGIONAL LABORATORIES.—The Secretary, acting through the Center for Disease Control, may enter into contracts with State public health laboratories to assist such laboratories in the conduct of tests to determine the presence and quantity of carcinogenic and other toxic substances in humans. There are authorized to be appropriated for the fiscal year ending September 30, 1978, $3,000,000 for contracts under this subsection.

(p) ADMINISTRATION OF SECTION.—The Secretary shall establish within the Department of Health, Education, and Welfare and under the direct supervision of the Assistant Secretary for Health an identifiable administrative unit which shall be responsible for coordination of the regulatory functions authorized by this section and the laboratory certification and regulatory functions authorized by titles XVIII and XIX of the Social Security Act.

(q) ANNUAL REPORT.—Not later than January 1, 1979, and January 1 of each succeeding year the Secretary shall make a report to the Congress (1) respecting the accuracy of tests and procedures performed by clinical laboratories during the preceding fiscal year, and (2) evaluating the effect of the costs of clinical laboratory tests and procedures on the overall cost of health care services and the relation of the costs of such tests and procedures to the costs of the health care services for which the tests and procedures are conducted.

SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

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Part A—General Provisions

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PROCEDURES FOR DETERMINING REASONABLE COST AND REASONABLE CHARGE

SEC. 1132. In determining the amount of any payment for a clinical laboratory service (other than such a service which is provided by a clinical laboratory which is located in a hospital and which provides services primarily in connection with the furnishing by the hospital of other inpatient or outpatient services) furnished under title XVIII, under a program established pursuant to title V, or under a State plan approved under title XIX, no reimbursement will be available for any element of the cost or charge for such service to the extent that such element is—

(1) a commission or finder's fee, or

(2) an amount payable for any facility (or part or activity thereof) under any rental or lease arrangement, where such amount (A) is unrelated or disproportionate to the market value of the facility (or part thereof), or (B) is, directly or indirectly, determined, wholly or in part, as a per centum, fraction, or portion of the charge or cost attributed to the laboratory service.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

Part C—Miscellaneous Provisions

Definition of Services, Institutions, etc.

Sec. 1861. For purposes of this title—

Spell of Illness

(a) * * *

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Medical and Other Health Services

(s) The term "medical and other health services" means any of the following items or services;

(1) physicians' services;

(2) (A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study; and

(D) outpatient physical therapy services;

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for a reduction of fractures and dislocations;

(6) durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) or (j)(1) of this section), whether furnished on a rental basis or purchased;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) including replacement of such devices; and

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

*[No diagnostic tests performed in any laboratory which is independent of a physician's office or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

[(10) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A)

*[Effective two years after the date of enactment of this Act.]

is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality, responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

[(11) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.]

No diagnostic test performed in any laboratory shall be included in paragraph (3) unless such laboratory meets applicable Federal or State licensing requirements under section 353 of the Public Health Service Act.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which—

(12) would not be included under subsection (b) if it were furnished to an inpatient of a hospital; or

(13) is furnished under arrangements referred to in such paragraph (2)(C) unless furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.

None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

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Use of State Agencies To Determine Compliance by Providers of Services With Conditions of Participation

SEC. 1864. (a) The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether a laboratory meets the requirements of *[paragraphs (10) and (11)] *the second sentence* of section 1861(s), or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1861(p)(4). **The Secretary may not make an agreement under the first sentence with a State for the purpose of determining whether a laboratory meets the requirements of the second sentence of section 1861(s) unless, as determined under section 353 of the Public Health Service Act, such State has primary enforcement responsibility for the regulation of clinical laboratories.* To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, or home health agency (as those terms are defined in section 1861) may be treated as such by the Secretary. Any State agency which has such an agreement may (subject to approval of the Secretary) furnish to an extended

care facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1861(j). Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, laboratory, clinic, agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place the pertinent findings of each such survey relating to the compliance of each such health care facility, laboratory, clinic, agency, or organization with (1) the statutory conditions of participation imposed under this title and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care or services by any such facility, laboratory, clinic, agency, or organization.

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Part C—Miscellaneous Provisions

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Penalties

SEC. 1877. (a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this title,

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to any such benefits or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized, or

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than one year, or both.

(b) Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—

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*Effective three years after the date of enactment of this Act.

(1) kickback or bribe *in the form of money or any other thing of value* in connection with the furnishing of such items or services or the making or receipt of such payment, or

(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services,

shall be guilty of a [misdemeanor] *felony* and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than [one year] *three years*, or both.

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TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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State Plans for Medical Assistance

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

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(23) provide that any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services; and a State plan shall not be deemed to be out of compliance with the requirements of this paragraph or paragraph (1) or (10) solely by reason of the fact that the State (or any political subdivision thereof) *A* has entered into a contract with an organization which has agreed to provide care and services in addition to those offered under the State plan to individuals eligible for medical assistance who reside in the geographic area served by such organization and who elect to obtain such care and services from such organization, *or (B) has made arrangements through a competitive bidding process or otherwise for the purchase of laboratory services referred to in section 1905(a)(3), if the Secretary has found that (i) adequate services will be available under such arrangements, (ii) such laboratory services will be provided only through laboratories which during the three-year period beginning on the date of enactment of the Clinical Laboratory Improvement Act of 1976 meet the requirements of section 1861(e)(9) or paragraphs (10) and (11) of section 1861(s) and after the expiration of such period are licensed in accordance with section 353 of the Public Health Service Act, and (iii) charges for services provided under such arrangements are made at the lowest rate charged (determined without regard to administrative costs which are related solely to the method of reimbursement for such services) for comparable services by the provider of such services, or, if charged for on a unit price basis, such charges result in aggregate expenditures not in excess of expenditures that would be made if charges were at the lowest rate charged for comparable services by the provider of such services*;

(28) provide that any skilled nursing facility receiving payments under such plan must satisfy all of the requirements contained in section 1861(j), except that the exclusion contained therein with respect to institutions which are primarily for the care and treatment of mental diseases and tuberculosis shall not apply for purposes of this title, *and provide that any laboratory services paid for under such plan must be provided by a laboratory which during the three-year period beginning on the date of enactment of the Clinical Laboratory Improvement Act of 1976 meet the requirements of section 1861(e)(9) or paragraphs (10) and (11) of section 1861(s) and after the expiration of such period are licensed in accordance with section 353 of the Public Health Service Act*;

* * * * * * *

(30) provide such methods and procedures relating to the utilzation of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care *and, in the case of laboratory services referred to in section 1905(a)(3), such payments do not exceed the lowest amount charged (determined without regard to administrative costs which are related solely to the method of reimbursement for such services) to any person or entity for such services by that provider of laboratory services, and in the case of laboratory services billed for by a physician or laboratory but performed by another person or entity which is not in the employ of the physician or laboratory, do not exceed the lowest amount charged to any person or entity for the service plus, at the option of the State and if it is determined to be reasonable under regulations prescribed by the Secretary, a nominal charge for any necessary professional service performed by the physician*;

* * * * * * *

Penalties

SEC. 1909. (a) * * *

(b) Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title and who solicits, offers, or receives any—

(1) kickback or bribe *in the form of money or any other thing of value* in connection with the furnishing of such items or services or the making or receipt of such payment, or

(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services

shall be guilty of a [misdemeanor] *felony* and upon conviction thereof shall be fined not more than $10,000 or imprisoned for not more than [one year] *three years*, or both.

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